INSTRUCTIONS FOR USE

STARRSED AUTO COMPACT INSTRUCTIONS FOR USE

Version 1.07 MRN-074-EN

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Document history overview

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1.06	November 2013	History screen Quality control Trouble shooting	• Introduction of chapter Quality Control	H. Schavemaker
1.05	February 2013	History screen Maintenance screen Maintenance Error list	• Addition print result header • Hazy aspect not suppressed in case of limit error • Prime/Clean text • Maintenance items up to level 4 included • Reagent installation • Error 19 added	H. Schavemaker
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1.03	January 2012		• Annual update and publication	
1.02	June 2011	Turn off	• It is not a problem if the StaRRsed Auto-Compact is on all the time. However,....>	H.E. van Dijk

1.01	February 2011	Sample screen History screen	• Rack pictogram explained	H.E. van Dijk
1.00	July 2010	All	• Reviewed	K. Artz
Preliminary	July 2010	All	• Manual build from MRN-71	K. Artz

CONTENTS

1. INTRODUCTION

The **StaRRsed Blood Sedimentation Rate Instrument** (hereafter called StaRRsed Auto-Compact) is an in vitro diagnostic medical device that automatically carries out the erythrocyte sedimentation rate analysis according to the **Westergren** method, conforming to CLSI approved standard H02-A5, using closed sample tubes filled with citrate or EDTA blood.

The StaRRsed Auto-Compact is an advanced ESR system that offers many unique features and benefits over the traditional ESR procedures. Automating this method has the following advantages:

- The Westergren pipettes are always filled to the correct level.
- Using closed sample tubes reduces the possibility of contamination for the user and environment.
- Standard glass Westergren pipettes are used, in which the measurement can be corrected to a constant temperature (18 C° Celsius). Even small ab normalities can be detected over a longer period of time, irrespective of where and when the blood sample was taken.
- Every sedimentation measurement is directly linked to an identified sample, so that a manual work sheet is unnecessary. Patient ID errors are reduced to a minimum by using the bar-code reader.
- In the EDTA mode, the accuracy of dilution of EDTA blood with citrate is considerably better than manual dilution achieved either by "tipping off" or using evacuated blood collection tubes pre-filled with citrate solution.
- The data can be send to your Lab Information System.
- The used sedimentation pipettes are automatically washed and dried.
- Minimum sample volume is 1.4 ml for the StaRRsed Auto-Compact.
- The StaRRsed Auto-Compact has fully automatic sample loading.
- The Rack system can work with a variety of hematology analyzer racks with most common EDTA blood sample tubes.
  The system uses rack adapters and is set up for a specific type of rack.
- Windows based System Software is running on an external computer.

1.1. Explanation of available documentation

Manuals for the StaRRsed Auto-Compact are available on three levels: for the operator, the supervisor and the service engineer.

The following manuals are available:

1. Instructions for Use (IFU)
   Intended for the operator: Contains instructions for normal operation, safety, preventive maintenance and trouble shooting procedures to solve the most common problems. Available in several languages.

2. User Manual (UM)
   Intended for the lab supervisor. Contains information from the IFU and additional information concerning settings, service, higher maintenance levels and trouble shooting procedures to solve more complicated problems. Only available in English.
3. Service Manual (SM)
   Intended for trained service engineers. Describes maintenance, servicing and repair of the instrument in detail. Contains detailed descriptions of parts, assembly drawings, modifications, extended trouble shooting, flow diagrams etc. Only available in English.
4. Installation Manual (IM)
   Intended for trained service engineers. Contains instructions and procedures for installation and start-up. Only available in English.

Manuals are available in PDF and HTML-format and can be downloaded from http://www.rrmechatronics.com.

2. INSTRUMENT DESCRIPTION

The **StaRRsed Auto-Compact** can accommodate sample racks from different manufacturers. The individual rack with the blood samples is snapped into the Mechatronics rack adapter and need only be placed on the entry platform of the StaRRsed Rack unit.
The operator simply presses the button "Sample mode" and walks away.
The instrument picks up the rack and mixes the blood by rotating the rack 8 times, as recommended by the ICSH. Barcode labels are read and, if an ESR has been requested, blood is aspirated from the sample tube. Thereafter the Rack is rotated one time to ensure each blood sample is thoroughly mixed and the sample is picked up to be aspirated. Aspiration takes place via Mechatronics proprietary double needle mechanism.

The citrate dilution takes place in a 4+1 ratio and is achieved with ± 3% accuracy.

Eighty-four Westergren pipettes are housed in the carousel. Each is of precision bore glass. After each cycle, the pipette is cleaned automatically with low foam detergent followed by a drying cycle.

The fill line is back-flushed using saline solution.
The temperature is corrected to the standard value of 18℃ and ESR's may be read after one hour or 30 minutes. A foretell one-hour result is presented in the 30-minute mode.

The **StaRRsed Auto-Compact** can be interfaced bidirectionally with Laboratory Information Management Systems (LIMS) through a variety of interface protocols.

Results of the test are expressed in millimeters. This data together with the patient ID number is sent to the Laboratory Information System along with the sedimentation time used (60 or 30 minutes), the temperature and the dilution ratio.

The **StaRRsed Auto-Compact** analyzer consists of the following units:

StaRRsed Compact analyzer

- ESR measuring instrument with a belt holding 84 precision's bore glass Westergren pipettes.
- Automated aspiration of the sample tube.
- Automated dilution of EDTA blood sample with citrate.
- Automated measurement of ESR after 30 or 60 minutes.
- Automated cleaning and drying of pipettes.

StaRRsed Rack

- Add-on unit for sampling and rack handling.
- Barcode reader for sample identification.
- Rack transport unit.
- Automatic mixing of sample tubes before sampling.
- Needle unit.
- Diluter module.

PC with touch screen LCD monitor

- Windows based platform
- Dedicated instrument software
- Optional network connections
- USB port

Option:

- External bar code reader, which can be connected on the USB port of the Compact Analyzer. This bar code reader can be used for reagent handling and for ID-input in sample history search.

AutoCompact LS (special model)

This model uses large bulk containers for reagent supply instead of the 0.5-liter onboard containers. This means longer operation time without reagent preparation and no cleaning time. This model is delivered with longer level sensors and special reagents cover assembly.

2.1. Technical specifications

Technical specifications for the StaRRsed Auto-Compact:

StaRRsed AutoCompact instrument models:

Model	Model name	Catalogue number
	StaRRsed AutoCompact	**VERA109000**
	StaRRsed AutoCompact (LS)	**VERA109010**

ESR method:

ESR method	Westergren method
Temperature compensation method	R.W. Manley: J. clin Path (1957), 10, 354
30 minute method	R. Rogers: Medical Laboratory World 1994
Allowed blood specimen types	• For EDTA mode: Whole blood with < 1% EDTA anticoagulant. • For Citrate mode: Whole blood (4 vols.) with sodium citrate anticoagulant-diluent (1 vol.)
Automatic dilution	4 vols. blood + 1 vol. sodium citrate diluent (3.2% NaCl); accuracy ±3%
Reported result	mm after 1 hour

Reagents:

Reagents used	QRR 010931 Diluent QRR 010947 Disinfectant QRR 010933 Saline QRR 010934 Rinse solution De-ionized water
Reagent barcode label information	Code39

Blood volume:

Aspirated blood volume per sample	1.4 ml in EDTA mode 1.6 ml in Citrate mode

Rack and tube types:

Rack types	Abbott CD3500/3700 Abbott CD4000/Sapphire ABX Pentra 80 ABX Pentra 120 Bayer Advia Coulter LH750, DXH800 Coulter HmX Sysmex sample rack (low profile)
Sample tube types	Most commonly used brands/types. Closed tubes with concentric cap only.

Barcode reader:

Barcode reader type	CCD.
Reading capabilities	Most common barcode labels
	Code39, ITF, Industrial 2 or 5, CodaBar,
	EAN/UPC and CODE128.

Data storage:

Storage medium	30 Gb Hard disk on external PC
Storage capacity indication	approx. 5 Mb per 1000 samples (results and raw data)

2.2. Technical specifications contd.

StaRRsed Compact environment:

Sound level		Less than 65 dBA
Environment temperature		18 - 28 ℃
Relative humidity		10-90%

StaRRsed Compact:

Mains voltage	100/240V	50-60Hz
Fuse (20 x 5 mm)	Slow blow 220V	2.5 Amp
	Slow blow 110V	5.0 Amp
Power consumption	Standby	60 VA
	Maximum	500 VA
Heat output	Standby	70 Watt
	Full operation	360 Watt

Rack unit

Mains voltage		12 Volt DC from the StaRRsed Auto Compact
Power consumption		50 VA
Weight		21.5 Kg

StaRRsed Auto-Compact overall dimensions:

Dimensions	Width	1.100 mm
	Height	770 mm
	Depth	660 mm
	Weight	70 kg

StaRRsed Auto-Compact table size:

Table size (Min.)	Width (Exclusive space for PC)	1.100 mm
	Width (Including space for PC)	1.500 mm
	Depth	660 mm

3. INSTALLATION

The instrument must be unpacked, installed and checked by a trained engineer prior to first operation.
Detailed installation instructions are given in the StaRRsed Auto-Compact Installation manual.

4. GENERAL SAFETY INSTRUCTIONS

The instrument described in this manual is designed to be used by properly trained personnel only. For the correct and safe use of this instrument it is essential that both operating and servicing personnel follow generally accepted safety procedures in addition to the safety precautions specified in this manual.

- Execute your work according to this manual. Read the instructions before operating the instrument. Observe all cautionary markings in the manual and on the instrument. Keep this manual for future reference.
- Follow the bio safety procedures when working with blood-contaminated parts.
- Be cautious to prevent stinging during cleaning or replacing the needle assembly.
- Repair can only be executed by trained and qualified personnel.
- Wear protective clothing.
- When the instrument is running it is not allowed to:
  - Open and remove safety covers.
  - Touch moving parts.
- It is not allowed to give access to the instrument to a non-authorised person at any time.
- Whenever it is likely that safety-protection has been impaired, the instrument must be made inoperative and be secured against any unintended operation. The matter should then be referred to qualified technicians.
- Safety protection is likely to be impaired if, for example, the instrument fails to perform the intended measurements or shows visible damage or unusual smells, smoke, liquids are flowing out.

4.1. Safety warning

When there was an incident with the StaRRsed Auto-Compact which caused damage to the instrument, please notify your superior and your local equipment dealer before you continue using the instrument.

Example:

- A collision with a moving object or a person
- Something falling on the instrument
- Liquids spilling into the instrument

5. AUTO COMPACT PROGRAM

The StaRRsed Auto-Compact is controlled via an external computer on which runs the StaRRsed Auto-Compact software. The software functions are grouped on six tabbed screens. The software is controlled by mouse pointer or directly via the touch screen. A virtual keyboard is automatically displayed on screen, when numerical or alphanumerical input is required.

Normal operational screens are the SAMPLE and the HISTORY screen.
The REAGENTS screen is used to check the reagent levels and log reagent replacement.
To activate priming sequences and cleaning operations, the screen MAINTENANCE is used.
The SETTINGS and SERVICE screens are protected by a password to prevent accidental change of settings. The SERVICE menu is used for service and control purposes.

SAMPLE ***screen*** (on page 19)

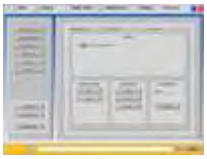
HISTORY ***screen*** (on page 24)

REAGENTS ***screen*** (on page 47)

MAINTENANCE ***screen*** (on page 50)

SETTINGS screen
(is not explained in this manual)

SERVICE screen
(is not explained in this manual)



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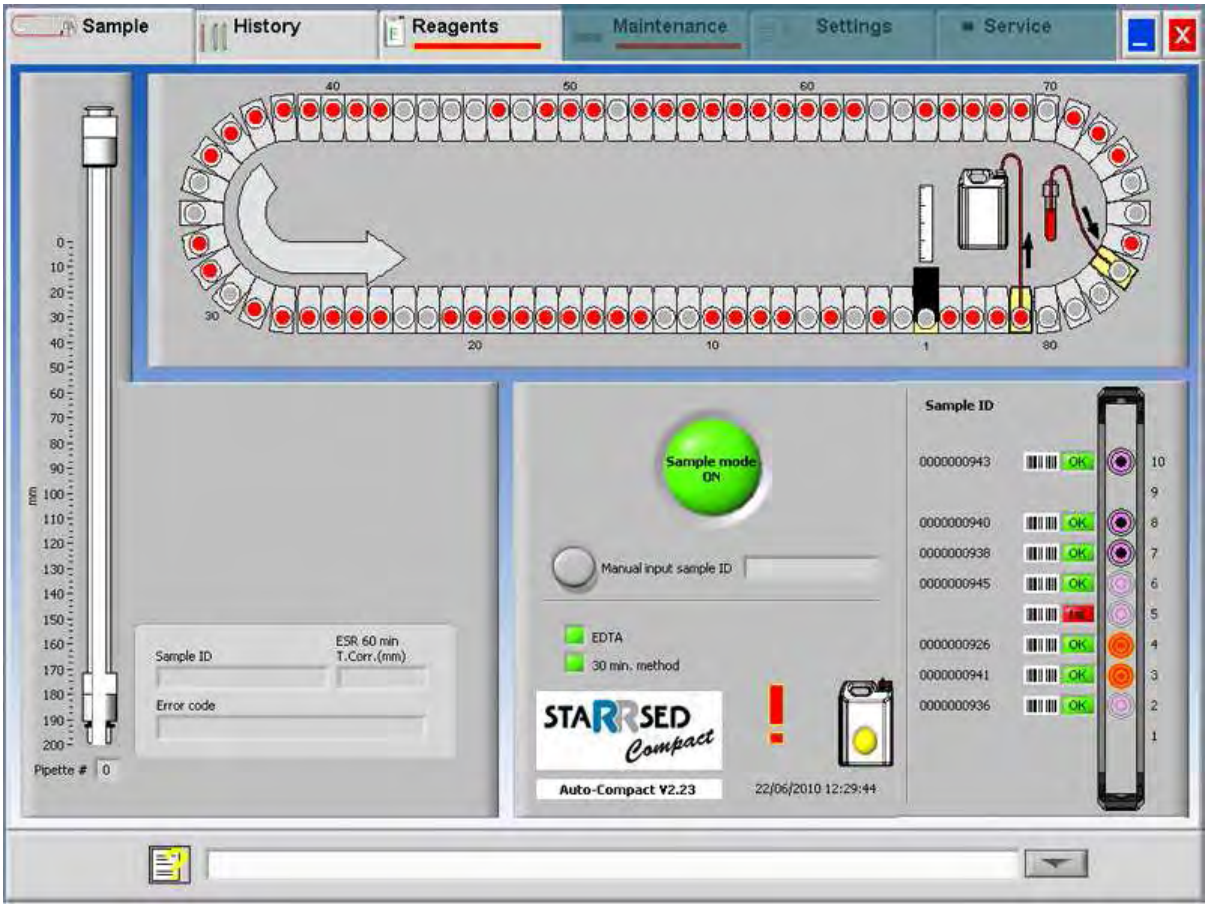
5.1. Software version

The latest software and manuals for the StaRRsed Auto-Compact can be downloaded from our website; www.rrmechatronics.com.

The following program description is valid for software up to version 5.01.

Software version V5.00 and higher runs only on a Windows 7 PC.

5.2. Sample screen



Display of the Status line in service mode:

The main menu is displayed during operation. To access other menus, select the required tab on the display and press the mouse button.
To access the other sub menus in the selected tab, select the required button and press the mouse button.

The following screens are selectable via the associated tabs:

1. SAMPLE ***screen*** (on page 19)

2. HISTORY ***screen*** (on page 24)
3. REAGENTS ***screen*** (on page 47)
4. MAINTENANCE ***screen*** (on page 50)
5. SETTINGS screen
6. SERVICE screen

The above picture is an example of the SAMPLE screen of the Compact in the normal operation mode. If the Service mode button with light is shown in the Status line, the Compact is running in the service mode. The User Manual button is also in the status line. Click this button to open the StaRRsed Auto-Compact User manual.

When the Compact is running in the Service mode all kinds of settings can be changed and the instrument will run with the changed settings.
For instance, when ESR time is set to 12 minutes, the Carousel will move according this time setting to be in time at the measure position.

When the Compact is running in the NORMAL MODE, the instrument uses the standard saved settings. For instance the ESR time is set back to 60 minutes or 30 minutes according the used method.

5.2.1. Carousel:

`Carousel`:
This is a graphical representation of the Compact carousel. When an ESR is required the carousel is moving to the Measure position. On the display, the belt is also moving accordingly. The decimal numbers next to the pipettes are the numbers on the pipette belt.
When a pipette is filled successfully, a red dot marks the filled pipette. In case of a failure the pipette is marked with a flashing red dot.
All the sample information can be found in tab HISTORY.

5.2.2. Measure station:

`Measure station`:
This is the position of the measure station where the ESR of the sample is measured.

5.2.3. Wash station:

`Wash station`: (Also named Rinse station)
This is the position where the sample is washed out of the pipette. The pipette is clean and dry after this process.

5.2.4. Fill station:

`Fill station`:
This is the position where the pipette is filled with a blood sample.

5.2.5. Pipette:

`Pipette`:
This is a graphical representation of the pipette. It is generated from the results of the ESR measurement. It can be used to locate possible air bubbles.

5.2.6. Rack:

`Rack`:
This is a representation of a rack in process. Empty positions indicate, that no sample tube was detected at that position.

The combinations of the pictograms have the following meaning:

Barcode could not be read (read failure).

Barcode was read correctly, but ESR is not required for this sample.

ESR is required and waiting to be done.

ESR was measured successfully.

ESR was measured, but with fill errors.

After processing the rack, the information of the rack is transferred to the DISPLAY RACK HISTORY (on page 29) screen.

5.2.7. Sample mode button:

Sample mode button:
This is the button to start or stop the run mode of the instrument.

5.2.8. Version information:

`Version information:`
Shows the version information of the software.

5.2.9. Manual input sample ID:

Manual input sample ID:
This window can be used for manual input of a barcode from a sample tube.

5.2.10. Sample information:

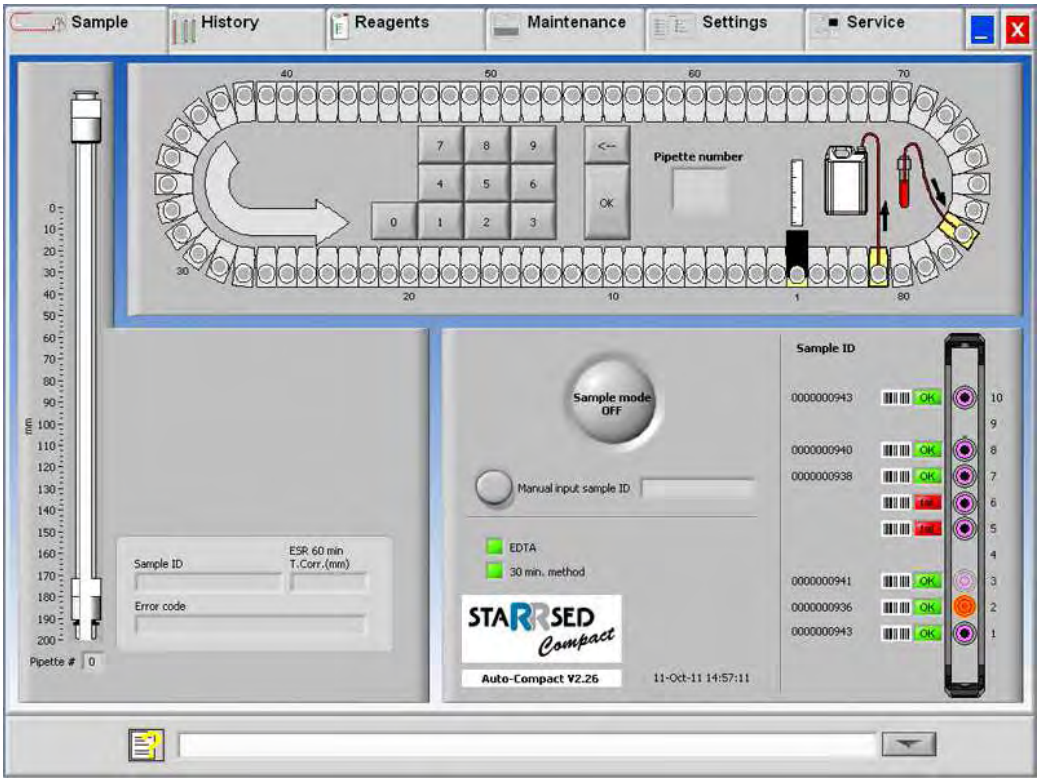
`Sample information:`
After measurement, the results of the sample are shown in this window. This window is refreshed after every new result of a sample.

5.2.11. Status:

`Status:`
Information about the current status of the instrument is shown here, such as the selected mode (EDTA or Citrate), selected method (60 or 30 minute) and symbols that draw attention to certain maintenance conditions or QC sample status (if applicable).

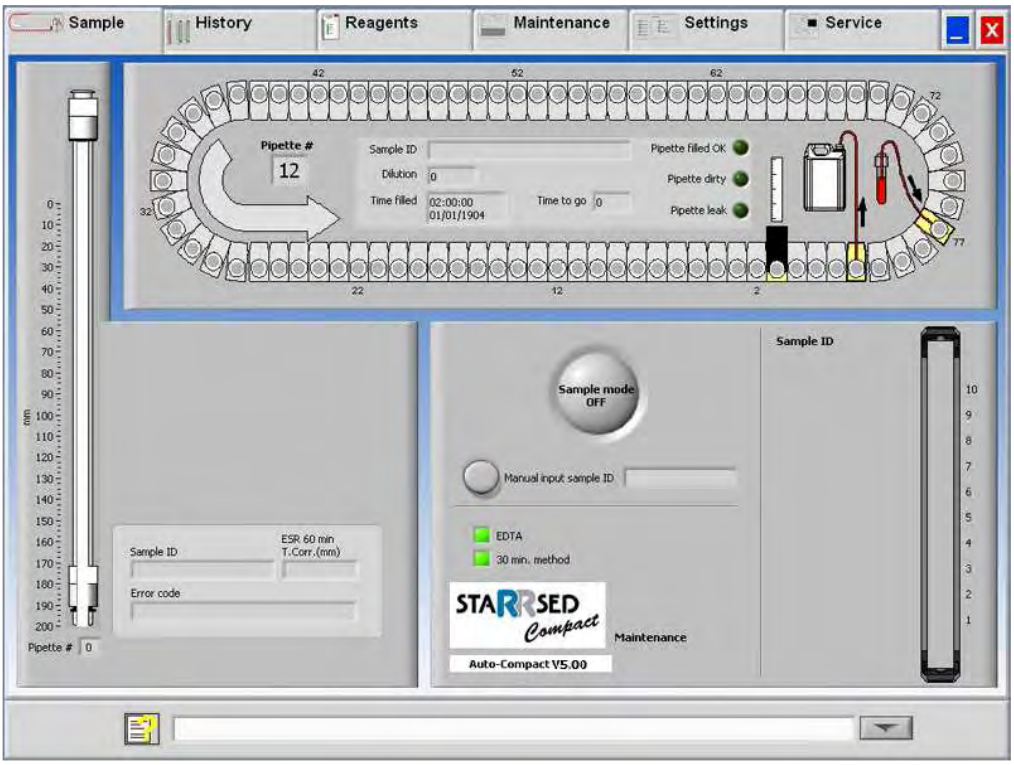
5.2.12. Sample screen with keyboard

To view the status of a specific pipette, click directly on the pipette itself or click the open space in the center of the belt representation. A virtual number pad is shown.



Type the number of the requested pipette and press the OK button. The following screen is shown.

5.2.13. Pipette information



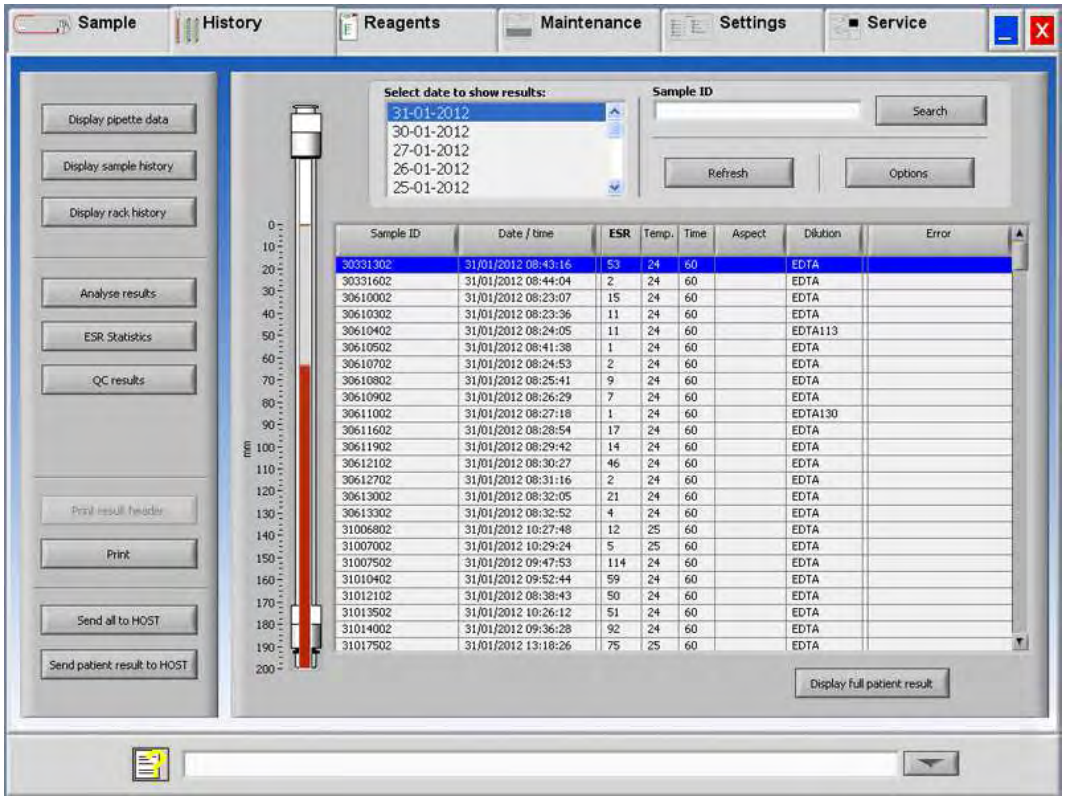
The following information is shown:

- Sample ID:
  The sample identification (barcode) of the sample tube.
- Dilution:
  The dilution rate of this sample as calculated during the aspiration process.
- Time filled:
  The date and time when the sample was aspirated.
- TIME TO GO:
  The number of minutes to wait until the sample will be measured.

The indicators at the right side show the current status of the selected pipette:

- Pipette filled OK:
  A sample has been aspirated into the pipette without problems.
- Pipette dirty:
  The sample has been measured and the pipette is marked to be washed when it reaches the rinse station. This indicator is also on when a sample could not be aspirated properly.
- Pipette leak:
  Reserved for future use.

5.3. History screen



In History the following options can be selected:

- DISPLAY PIPETTE DATA (on page 25)
  Use button PRINT to send the selected data to the printer.

- DISPLAY SAMPLE HISTORY (on page 26)
  - DISPLAY FULL PATIENT RESULT (on page 27)
    In Display sample history are the following options available:

    PRINT: Send the selected result to the printer.
    PRINT RESULT HEADER: Only if option Settings - General settings "PRINT AFTER MEASUREMENT" is switched **ON** it is possible to print a result header.
    SEND ALL TO HOST: Send all results again to the HOST.
    SEND PATIENT RESULT TO HOST: Send only the selected patient result to the HOST.

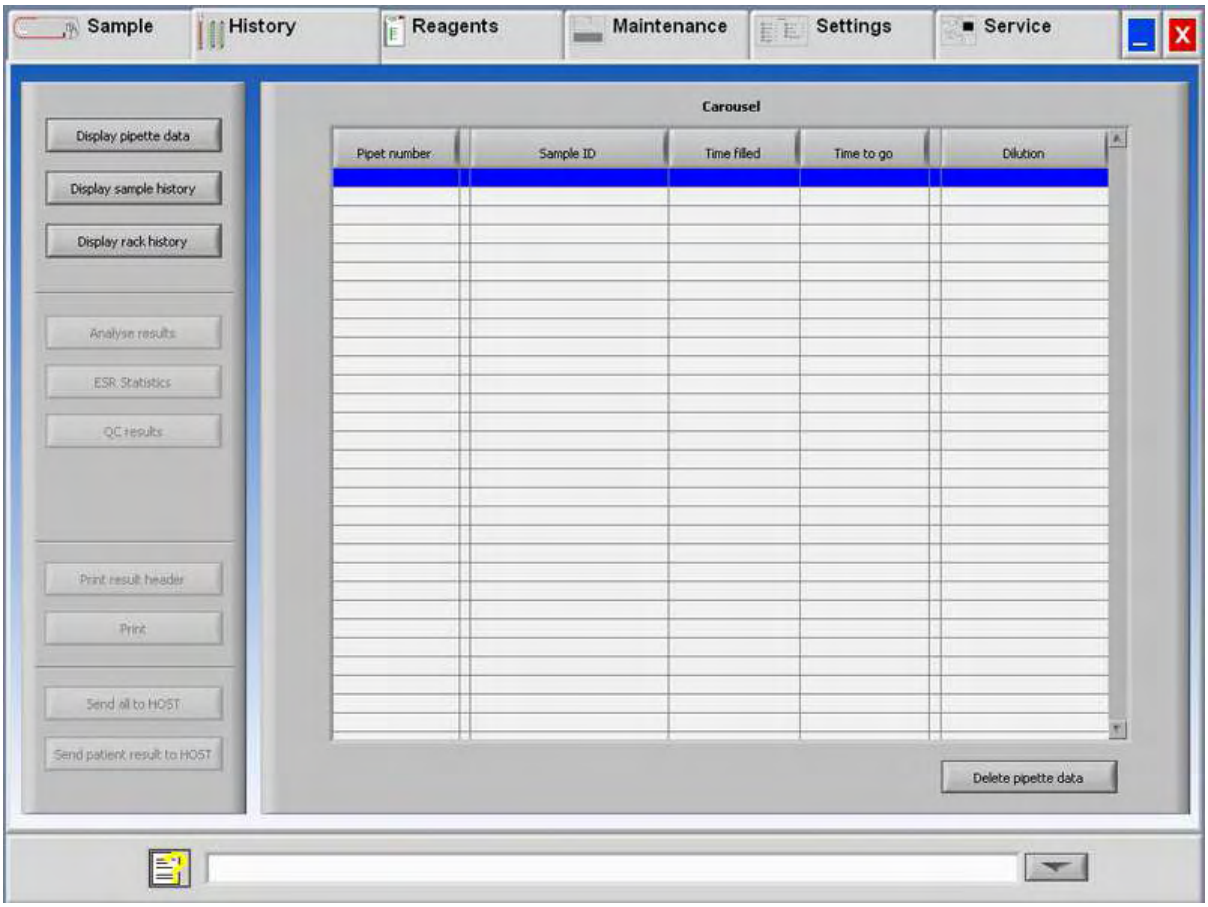
- DISPLAY RACK HISTORY (on page 29)
  - DISPLAY RACK DETAILS (on page 30)

- ANALYSE RESULTS (on page 41)

- ESR STATISTICS (on page 31)

- QC RESULTS (on page 32) (with StaRRsed Control)
  - LINKED QC ID'S (on page 40)

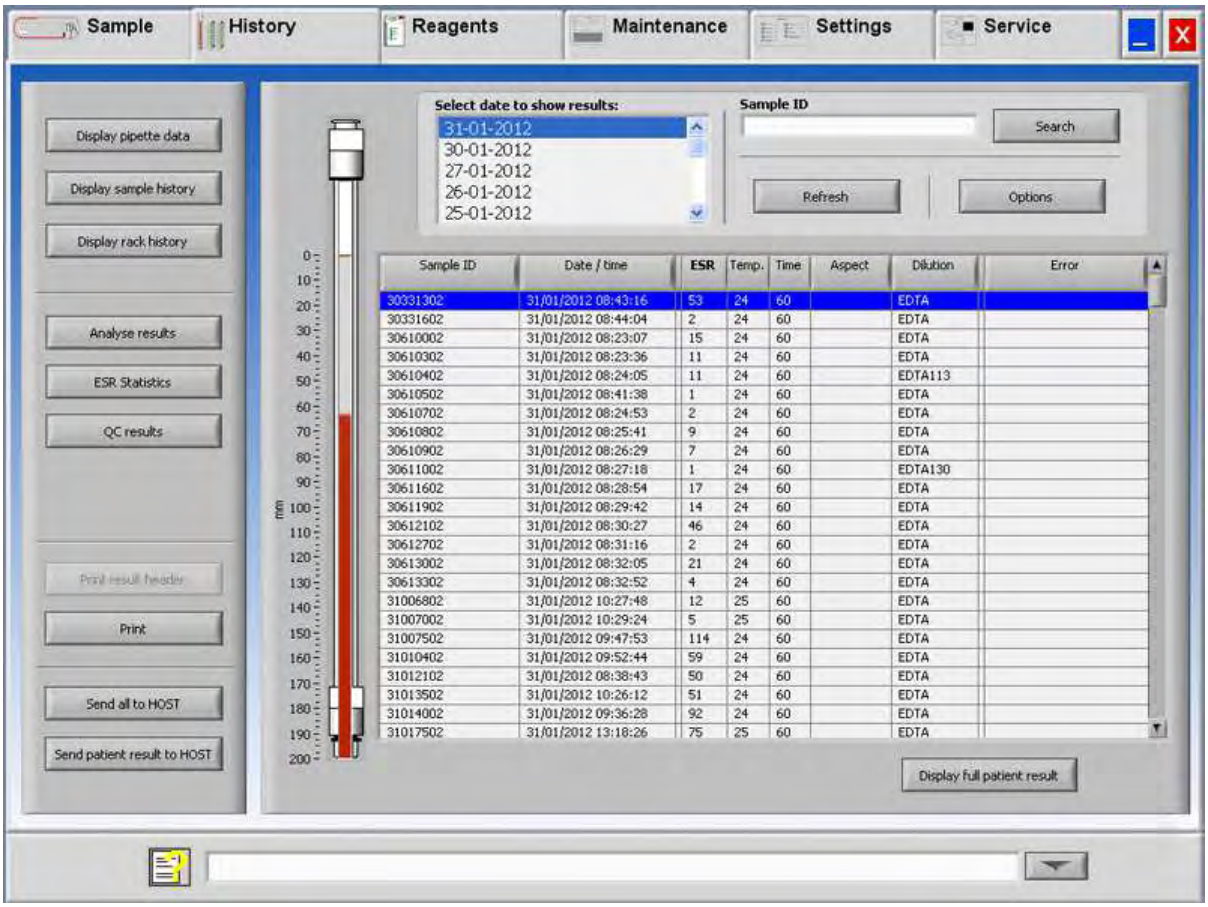
5.3.1. Display pipette data



This table shows information of the samples in the carousel during the selected ESR process time. After measuring the pipette, the pipette data is transferred to the sample history files.

In the header of the table the names of the columns are shown. Double-click the header of any column to sort the table by this column in ascending order.

5.3.2. Display Sample history



In the window Select date to show results: double click on the file name to select the results of the selected date.
Press **Refresh** to refresh the list of available files.
In the window Sample ID type the sample ID information and press **Search**.

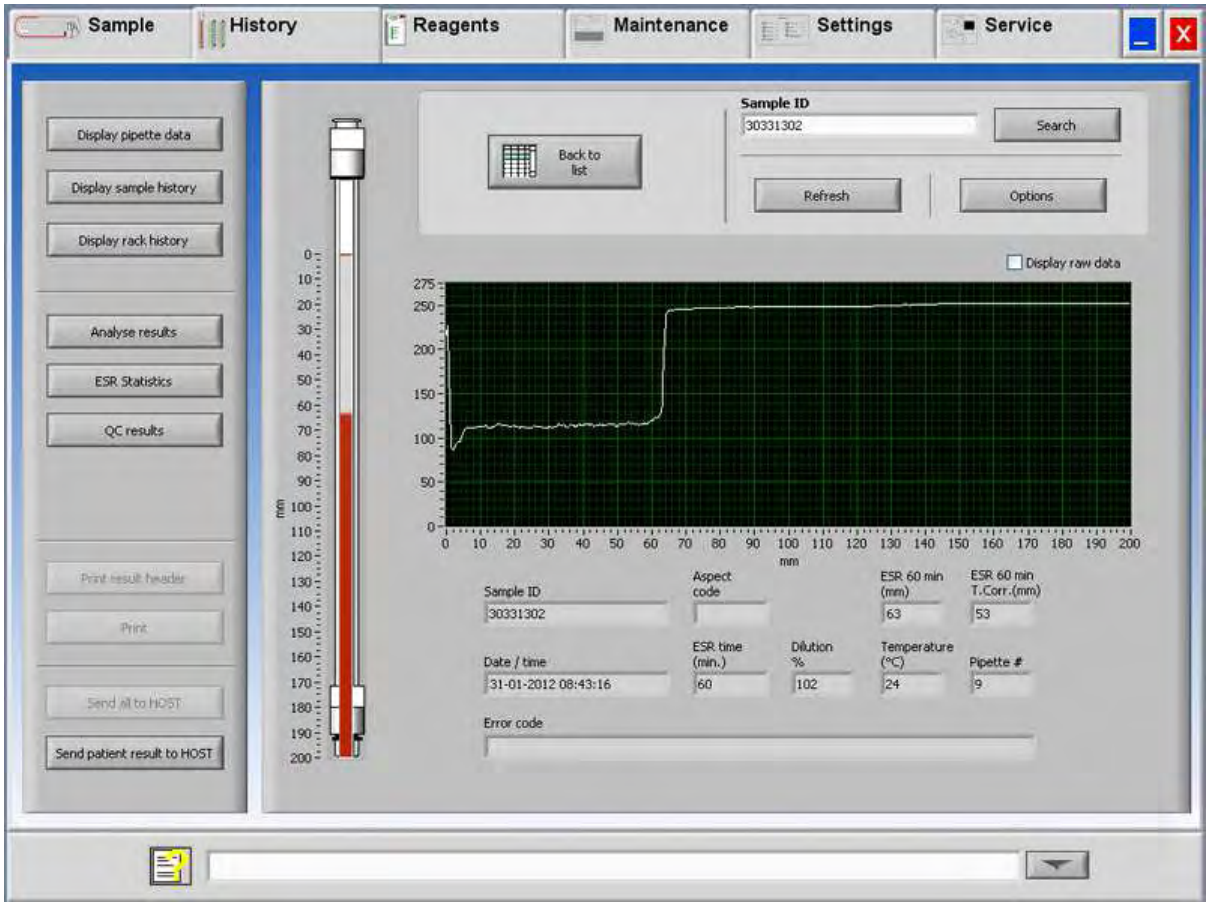
Press **Options** for the following search options:

- Show today's results.
- Show today's results from a selected time frame of the day.
- Show results of a number of past days. Default value is set for 7 days.
- Show results of a specific day.
- Show results of the range between the first selected date to the next selected date.

Select in the table a 'Sample ID' and click the button DISPLAY FULL PATIENT RESULT (on page 27) for more detailed information of the selected sample.

In the header of the table the names of the columns are shown. Double-click the header of any column to sort the table by this column in ascending order.

5.3.2.1. Display patient results



In the window Select date to show results: double click on the file name to select the results of the selected date.
Press **Refresh** to refresh the list of available files.
In the window Sample ID type the sample ID information and press **Search**.

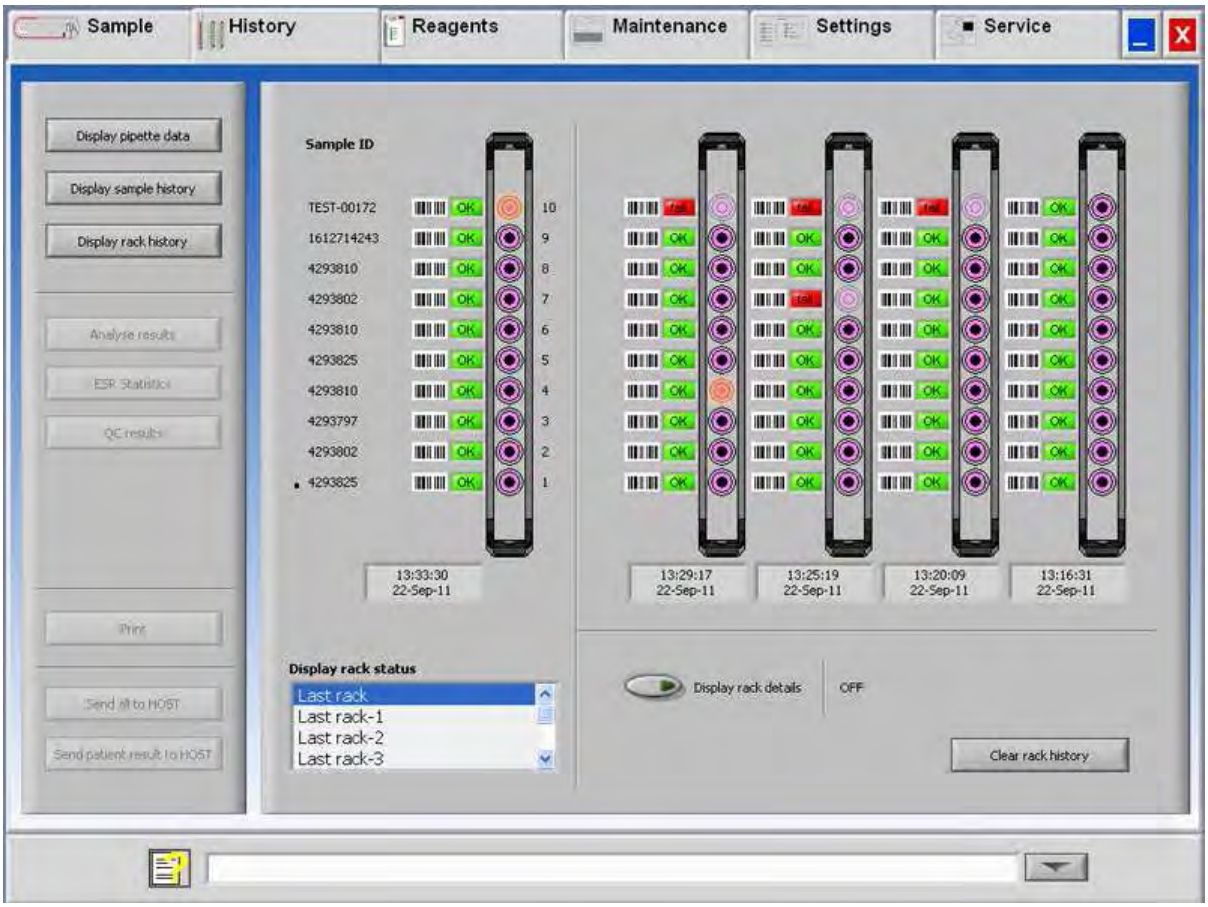
Press **Options** for the following search options:

- Show today's results.
- Show today's results from a selected time frame of the day.
- Show results of a number of past days. Default value is set for 7 days.
- Show results of a specific day.
- Show results of the range between the first selected date to the next selected date.

From the selected Sample ID detailed information is shown on this screen.

Sample ID	Sample Identification number
Aspect code	Shows the aspect code (e.g. Hazy <10)
ESR 30 min	The 30 minute method is used. This is the measured 30 minutes value.
ESR 60 min	When the 60 minute method is used, this is the *measured* 60 minutes value. When the 30 minutes method is used, this is the *calculated* 60 minutes value.
ESR 60 min T.Corr.	Temperature correction is used. This is the 60 minutes value corrected to 18℃.
Date / time	Date and time of the measurement of the result.
ESR time (min.)	Actual duration of the ESR.
Dilution %	The calculated dilution rate after aspiration of the sample.
Temperature (℃)	Room temperature at the time of th e measurement of the sample.
Pipet number	Pipette in which the sample was measured.
Error code	Shows any ESR error code (e.g. "Too many borders found").

5.3.3. Display rack history



After completion of the rack, the status of the rack is displayed here. The last 10 racks are stored and can be selected. The selected rack is displayed left (above the selection window). The previous 4 racks are also displayed and can be checked simultaneously. More detailed information of the selected rack is shown with DISPLAY RACK DETAILS (on page 30) **ON**.

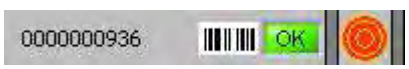
The combinations of the pictograms have the following meaning:

Barcode could not be read (read failure).

Barcode was read correctly, but ESR is not required for this sample.

ESR is required and waiting to be done.

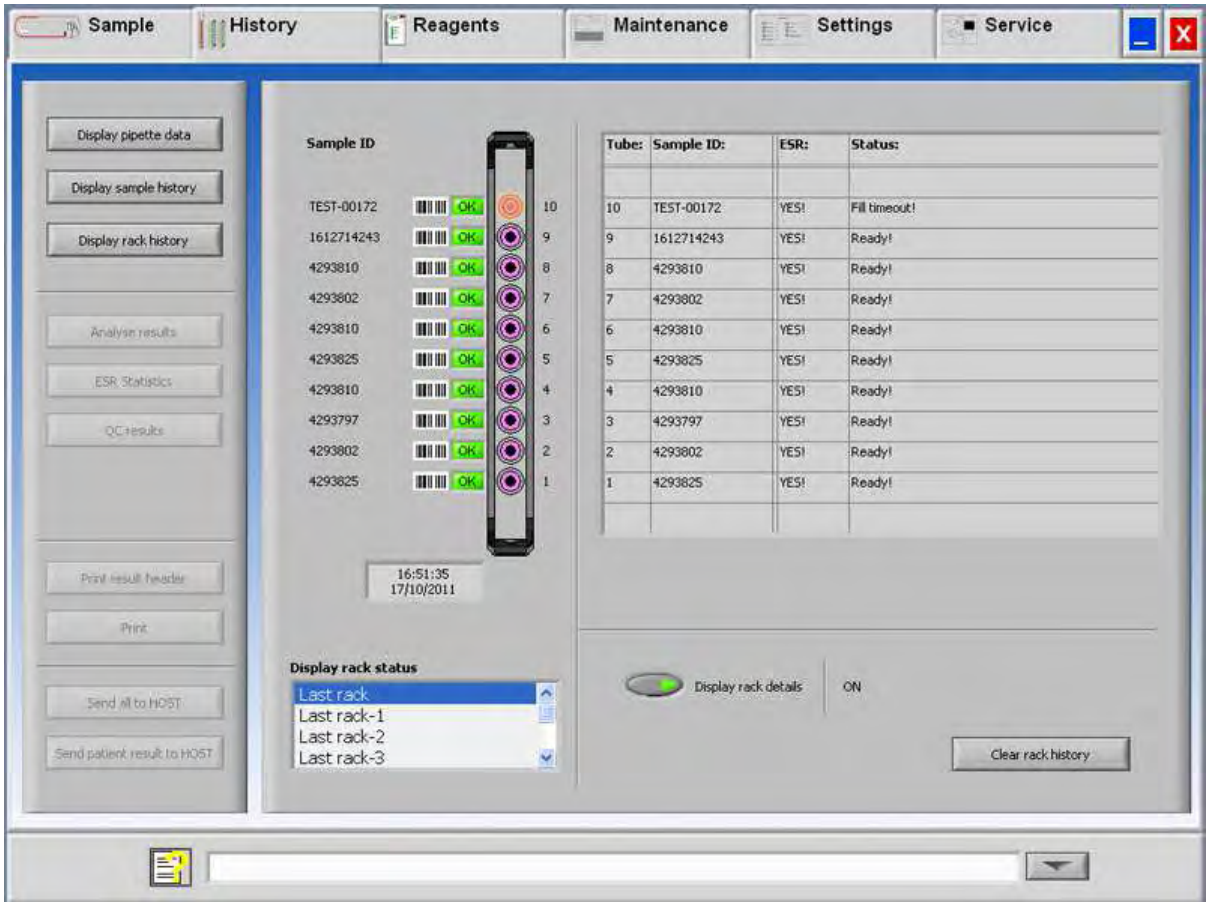
ESR was measured successfully.



ESR was measured, but with fill errors.

The Clear rack history button will clear the contents of the rack history file and restart to build-up a new rack history file.

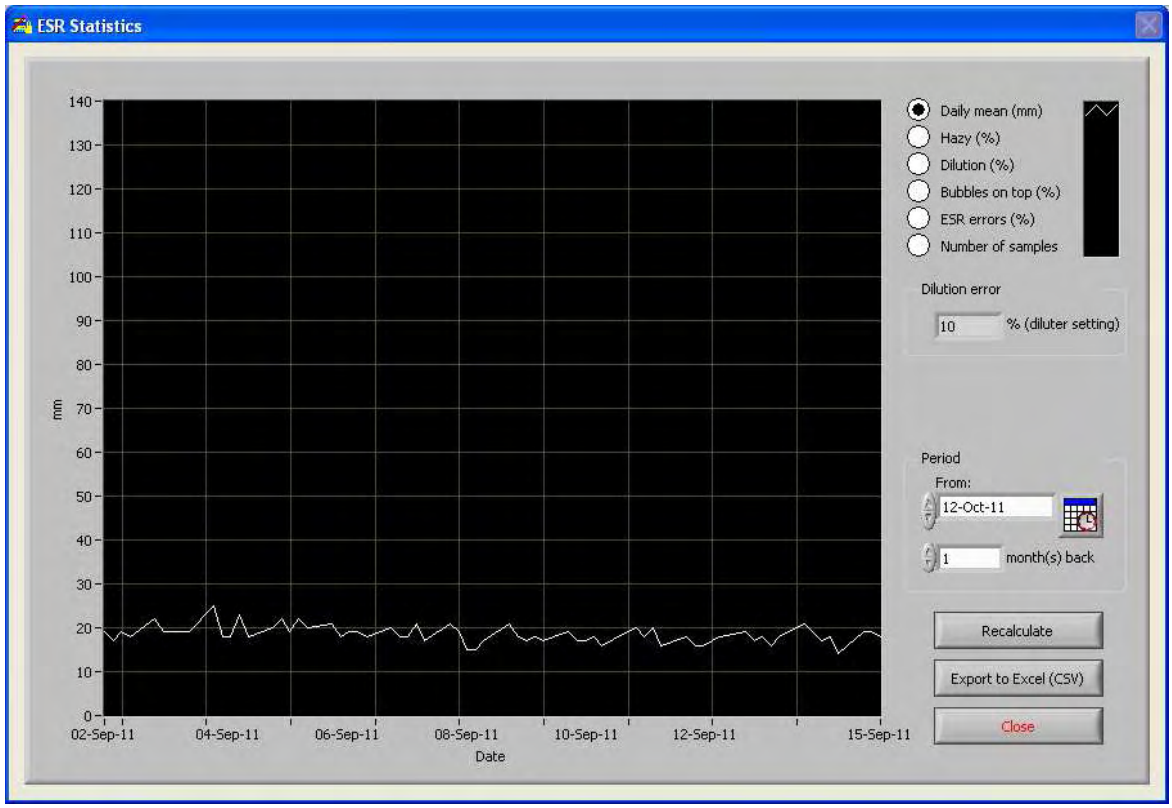
5.3.3.1. Display rack status



More detailed information of the samples in the selected rack is shown in the status table. The last 10 racks are stored and can be selected.

The Clear rack history button will clear the contents of the rack history file and restart to build-up a new rack history file.

5.3.4. ESR Statistics screens



A statistical graph is produced over a selected period. Make a selection of the following graphs;

- Daily mean (mm)
  Use this to check variations in the daily mean ESR.

- Hazy (%)
  Increasing hazy aspects are an indication for contamination of the instrument, see ***Aspect Hazy*** (on page 66)

- Dilution (%)
  Increasing dilution errors indicate the need for maintenance of the diluter system.

- Bubbles on top (%)
  Increasing samples with bubbles indicate the need for maintenance of the aspiration system, see ***Foam in column*** (on page 83)

- ESR errors (%)
  Increasing ESR errors may indicate the need for maintenance, see ***ESR Error*** (on page 64)

- Number of samples
  This can be used to document variations in work load.

5.3.5. QC Results screens

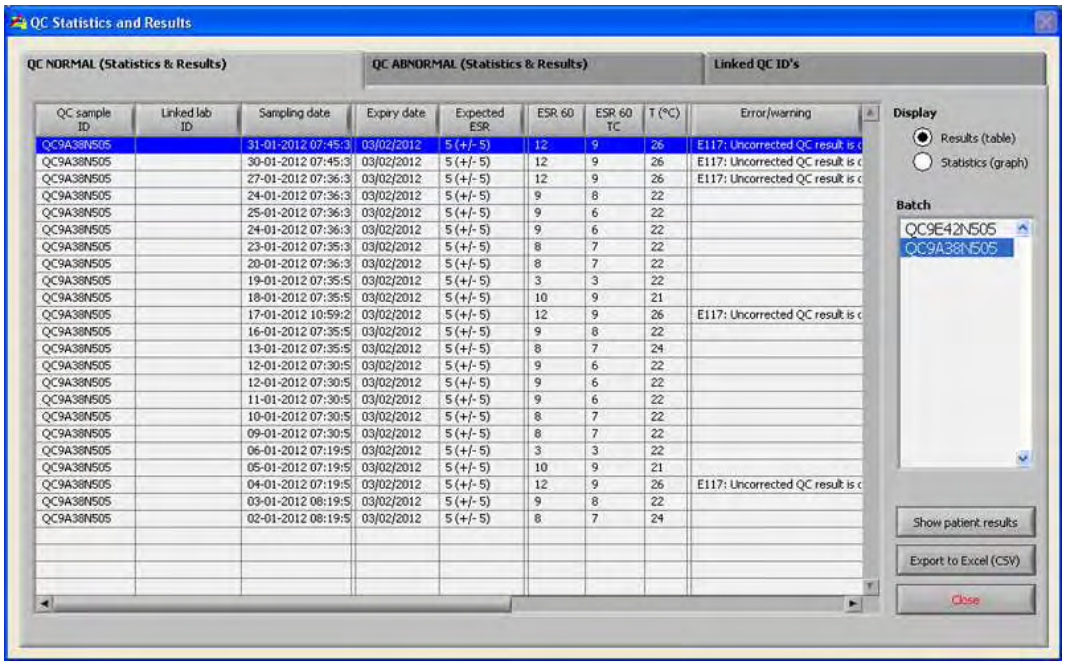
In this section results and statistics from QC samples are shown, in the section ***Linked QC ID's*** (on page 40) links can be created between QC sample ID's and Lab ID's.

The results from StaRRsed Control level N and level A are separated on their own tabs. Both tabs have the same layout and options. Results can be displayed in table format or in graphical format.

When the StaRRsed Control sample ID is used, results are only listed here. When Lab ID barcode is used, QC results are also listed in "Patient results".

Note: This part of the software can only be used in combination with StaRRsed Control as quality control material.

5.3.5.1. QC Normal results (table)



Display Results (table):
Results are shown in table as default.

QC sample ID:
Read from the barcode. The original StaRRsed Control barcode (=batch number)

Linked lab ID:
The Lab ID is given if it is linked to the StaRRsed Control sample ID

Sampling date:
The date and time when the QC sample was aspirated.

Expiry date:
If the StaRRsed Control expiry date is exceeded, it is not possible to continue with this QC sample. The sample is not measured, but the failed attempt is logged in the table.

Expected ESR:
This is the temperature corrected mean value (incorporated in the StaRRsed barcode) and the accepted range of deviation. The applicable values for the acceptable range depend on the user setting.

ESR 60:
Uncorrected result from QC sample.

ESR 60 T.CORR.:
Temperature corrected result from QC sample.

T(°C):
Temperature at which the sample was measured.

Error/Warning:
Only special QC errors are mentioned here, general ESR warnings/errors are mentioned in the next column.

After these columns additional data is shown: pipette number, dilution rate, ESR30, ESR time and Aspect. Scroll to the right.

Results are always shown with and without Temperature correction, independent of the setting TEMP. CORRECTION (ON or OFF).

The following options can be selected:

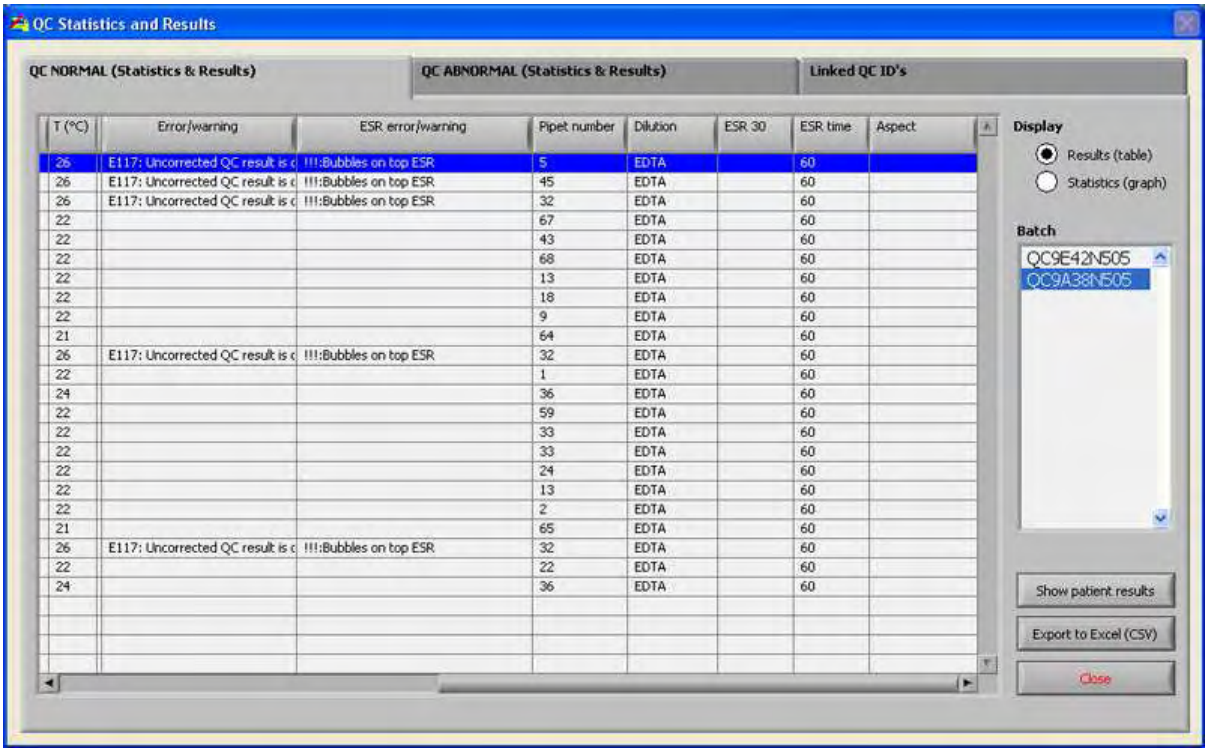
RELATED PATIENT RESULTS
This screen is simular to the "Display sample history" screen. The background colour of the patient history table is switched to light yellow to distinguish these QC related patient results from the standard patient history table. Depending on the frequency of QC samples, related patient results may span over multiple days and are listed per date.

EXPORT TO EXCEL (CSV)
Results can be exported to a .CSV file and imported in an MS Excel file for further analyses.

BATCH
All used batches of StaRRsed Control are shown, results are shown for chosen batch ID.

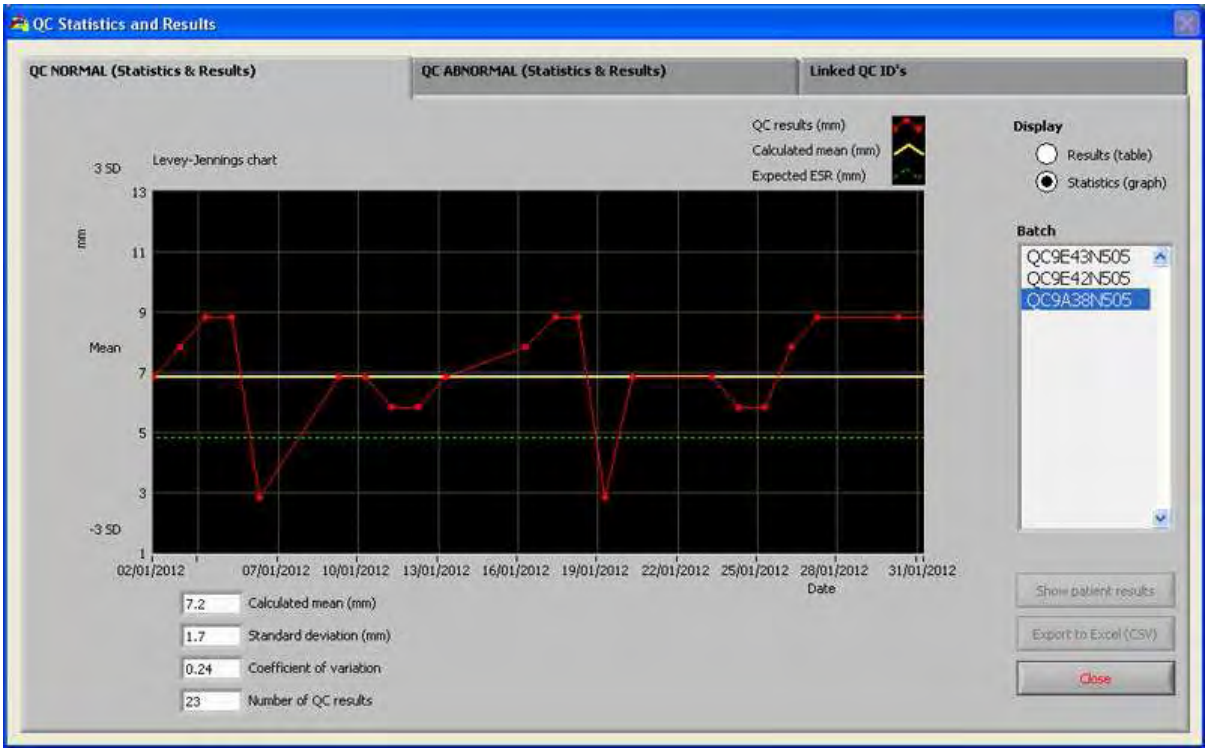
CLOSE
Return to History Screen.

5.3.5.2. QC normal results screen extended



After scrolling the general data from the QC results are shown.

5.3.5.3. QC normal results (graph)



Display Statistics (graph):

All QC results from the chosen StaRRsed Control batch are shown in a Levey-Jennings chart.

Shown in the graph:

- QC results (red) = values of measurements per date
- Calculated mean (yellow) = mean value of all QC results of the specific batch
- Expected ESR (green) = Assay mean value of chosen StaRRsed Control

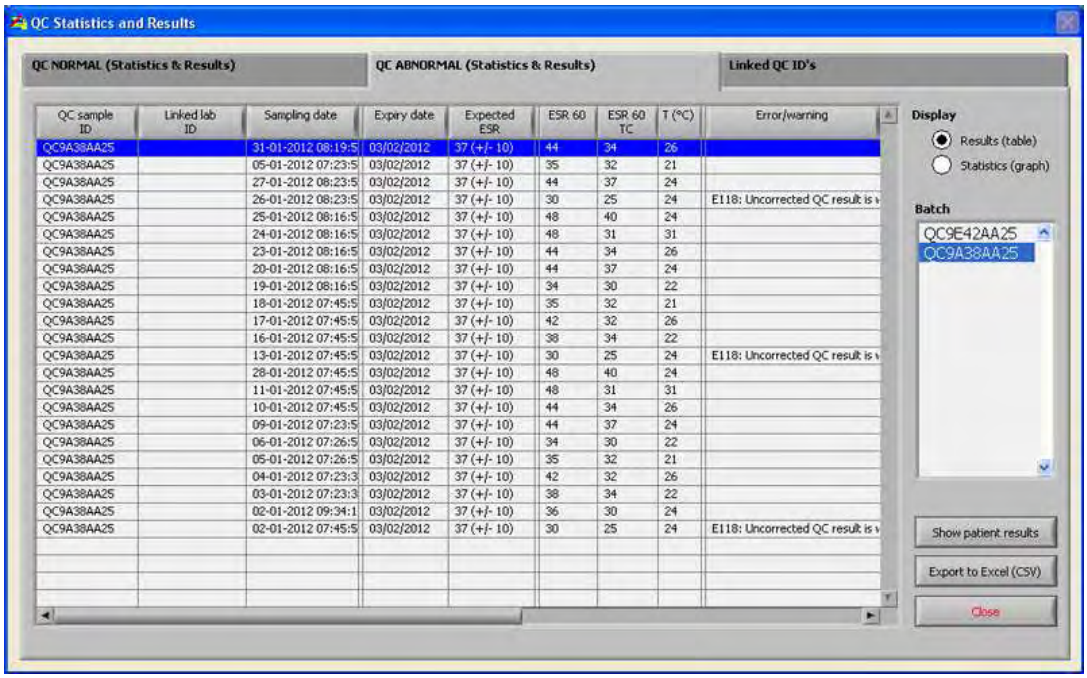
Shown as value:

- Calculated mean = mean value of all QC results of the specific batch
- Standard deviation = the average deviation of all QC results compared with the expected ESR
- Coefficient of variation = ratio of the standard deviation to the expected ESR, expressed in a percentage
- Number of QC results

This graph gives a first indication of the measuring stability of the StaRRsed Auto-Compact. Further analysis and identification of systematic errors have to be performed in the user's Quality Control System.

CLOSE
Return to History Screen

5.3.5.4. QC abnormal results (table)



The results from StaRRsed Control level A are shown.

Display Results (table)

QC sample ID:
Read from the barcode. The original StaRRsed Control barcode (=batch number)

Linked lab ID:
The Lab ID is given if it is linked to the StaRRsed Control sample ID

Sampling date:
The date and time when the QC sample was aspirated.

Expiry date:
If the StaRRsed Control expiry date is exceeded, it is not possible to continue with this QC sample. The sample is not measured, but the failed attempt is logged in the table.

Expected ESR:
This is the temperature corrected mean value (incorporated in the StaRRsed barcode) and the accepted range of deviation. The applicable values for the acceptable range depend on the user setting.

ESR 60:
Uncorrected result from QC sample.

ESR 60 T.CORR.:
Temperature corrected result from QC sample.

T(°C):
Temperature at which the sample was measured.

Error/Warning:
Only special QC errors are mentioned here, general ESR warnings/errors are mentioned in the next column.

After these columns additional data is shown: pipette number, dilution rate, ESR30, ESR time and Aspect. Scroll to the right.

Results are always shown with and without Temperature correction, independent of the setting TEMP. CORRECTION (ON or OFF).

The following options can be selected:

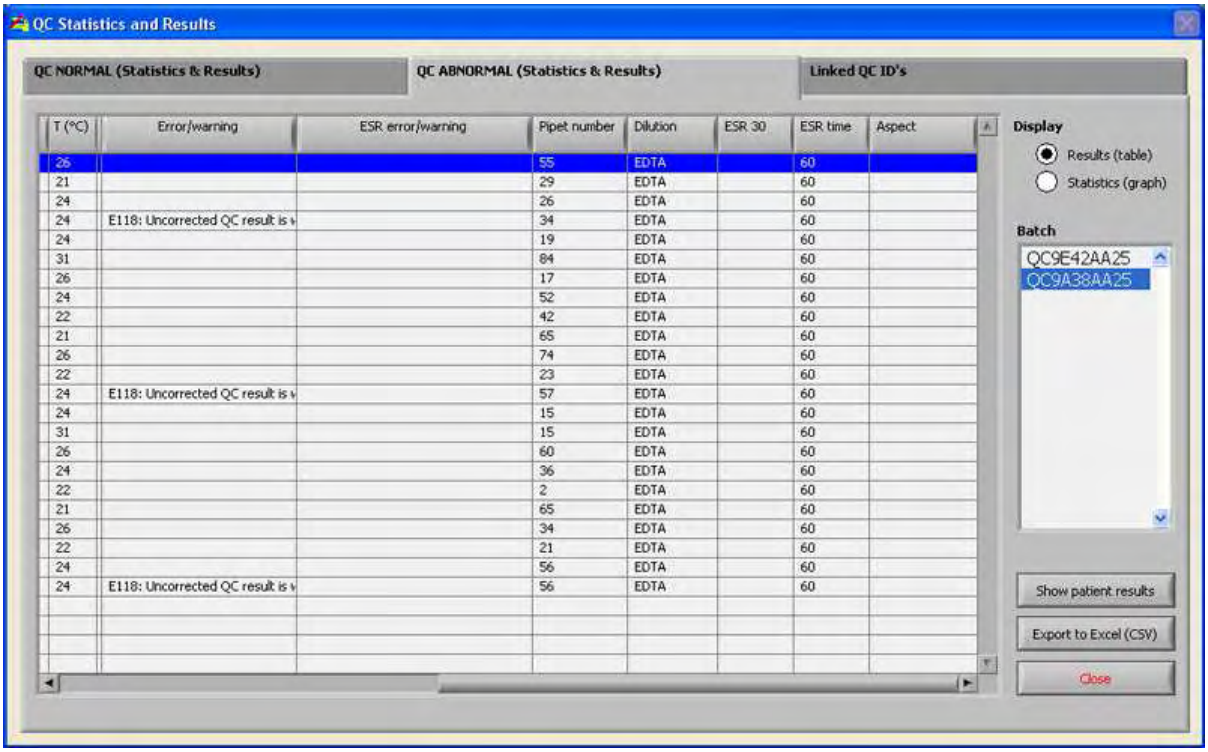
RELATED PATIENT RESULTS
This screen is simular to the "Display sample history" screen. The background colour of the patient history table is switched to light yellow to distinguish these QC related patient results from the standard patient history table. Depending on the frequency of QC samples, related patient results may span over multiple days and are listed per date.

EXPORT TO EXCEL (CSV)
Results can be exported to a .CSV file and imported in an MS Excel file for further analyses.

BATCH
All used batches of StaRRsed Control are shown, results are shown for chosen batch ID.

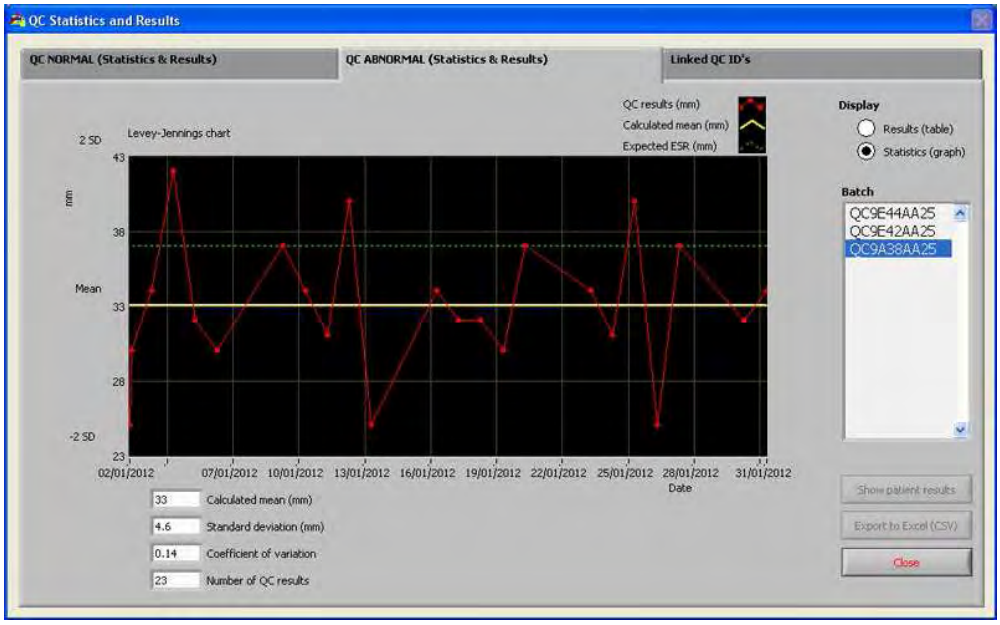
CLOSE
Return to History Screen.

5.3.5.5. QC abnormal results screen extended



After scrolling the general data from the QC results are shown.

5.3.5.6. QC abnormal results (graph)



Display Statistics (graph):

All QC results from the chosen StaRRsed Control batch are shown in a Levey-Jennings chart.

Shown in the graph:

- QC results (red) = values of measurements per date
- Calculated mean (yellow) = mean value of all QC results of the specific batch
- Expected ESR (green) = Assay mean value of chosen StaRRsed Control

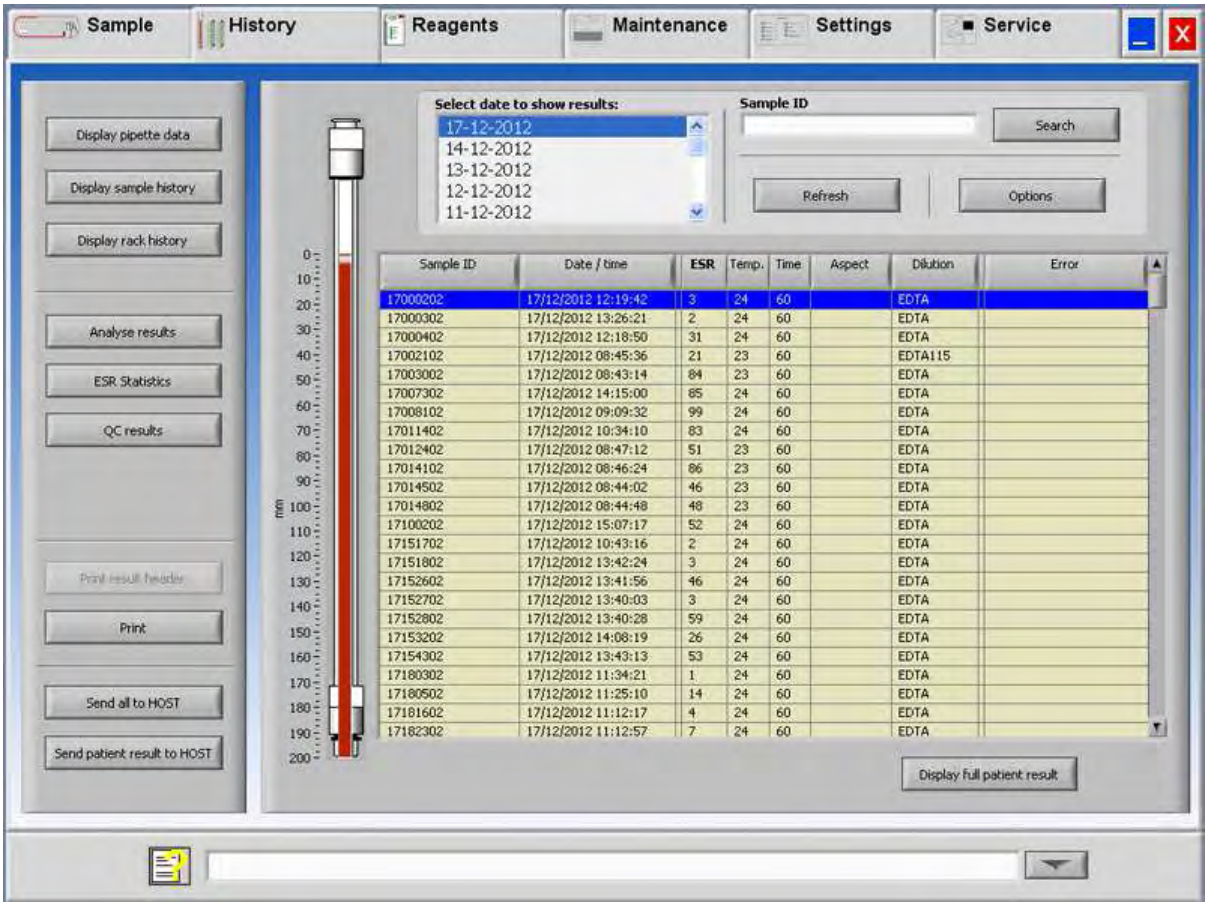
Shown as value:

- Calculated mean = mean value of all QC results of the specific batch
- Standard deviation = the average deviation of all QC results compared with the expected ESR
- Coefficient of variation = ratio of the standard deviation to the expected ESR, expressed in a percentage
- Number of QC results

This graph gives a first indication of the measuring stability of the StaRRsed Auto-Compact. Further analysis and identification of systematic errors have to be performed in the user's Quality Control System.

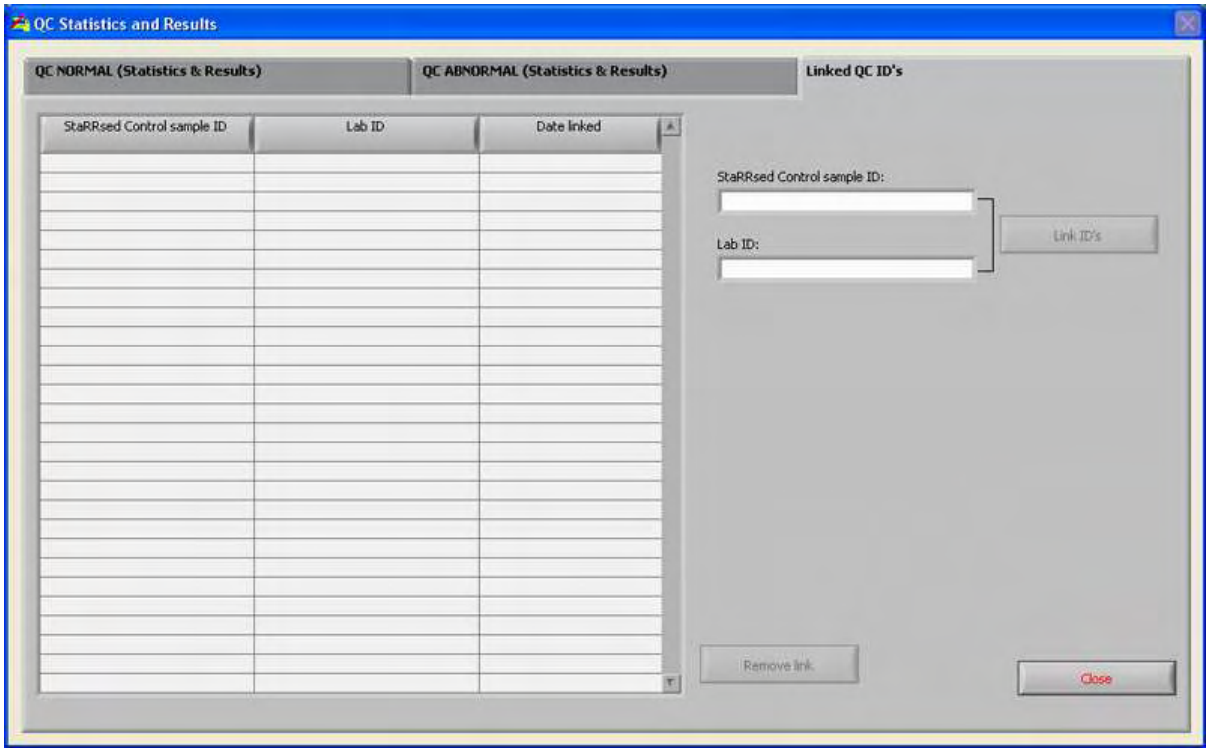
CLOSE
Return to History Screen

5.3.5.7. Display sample history (QC)



This screen shows all patient results that have been measured after the selected QC result and up to the following QC result. The results are presented in the layout of the "DISPLAY SAMPLE HISTORY (on page 26)" screen. Depending on the frequency of QC samples, related patient results may span over multiple days and are listed per date. All general ESR data and errors of QC samples are shown here.

5.3.5.8. Linked QC ID's



Use this screen to link the StaRRsed Control sample ID with a Lab ID or to check which links are active.

1. "StaRRsed Control sample ID": Enter the lot number or scan the barcode from the original StaRRsed Control tube label. If the original label is already covered by the Lab ID label, find the lot number and barcode on the package insert.
2. "Lab ID": Enter the patient number or scan the barcode from the label that the lab is using to identify the sample.
3. Click button "Link ID's" to add the linked ID's to the list. The "Date linked" will be added automatically.
4. Attach the Lab ID label on the StaRRsed Control sample tube so that the original barcode is completely covered to ensure that only the Lab ID barcode can be scanned by the StaRRsed Auto-Compact.

If the StaRRsed Control sample ID is not correct or the expiry date is exceeded, a message will be shown and the ID's are not added to the list.

To remove a link that will no longer be used, select the link in the table and click on "REMOVE LINK".

Depending on the optional setting "AUTOMATICALLY REMOVE LINKED QC ID AFTER RESULT", (SETTINGS - QC SETTINGS) the links can be removed automatically when a usable ESR result has been reported for this particular Lab ID.

5.3.5.9. QC Result analysis

Authorized staff should identify and differentiate acceptable/unacceptable random errors and trends and/or shifts in systematic errors from the statistical data. Depending on the users Quality Control Procedures analytical results could be accepted or rejected.

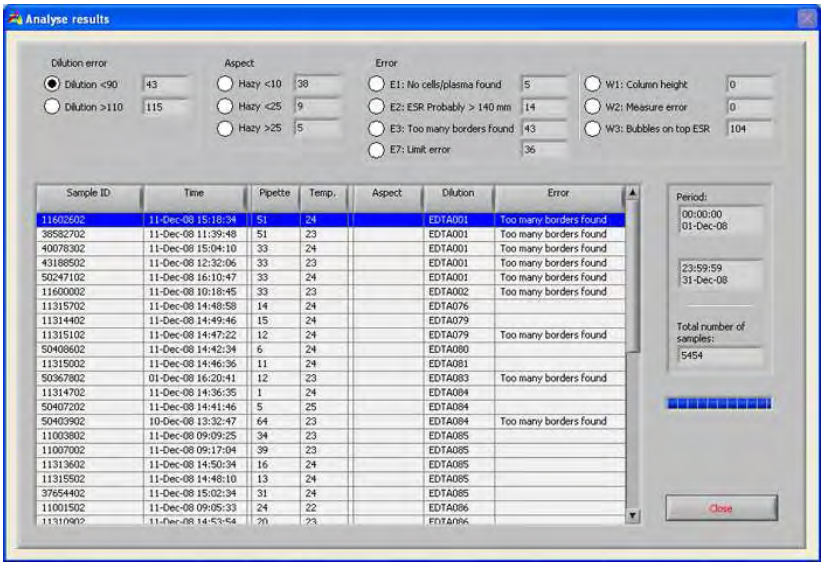
Changes in QC results can be gradual or abrupt. Gradual changes can be caused by contamination and incidental environmental variations. Abrupt changes can be caused by change of QC material batch or possible hardware errors.

If results are continuously out of range due to significant difference between calculated mean and control value, but the statistics show precise results with small deviations, it should be considered to expand the acceptable assay range with QC Settings.

If results are incidentally out of range it is advised to perform a daily maintenance and/or fill and clean step and then perform another QC sample step before releasing patient results.

If results are not send to the LIMS QC Results can be exported to MS Excel CSV files for further analysis in lab's own Quality Control data system.

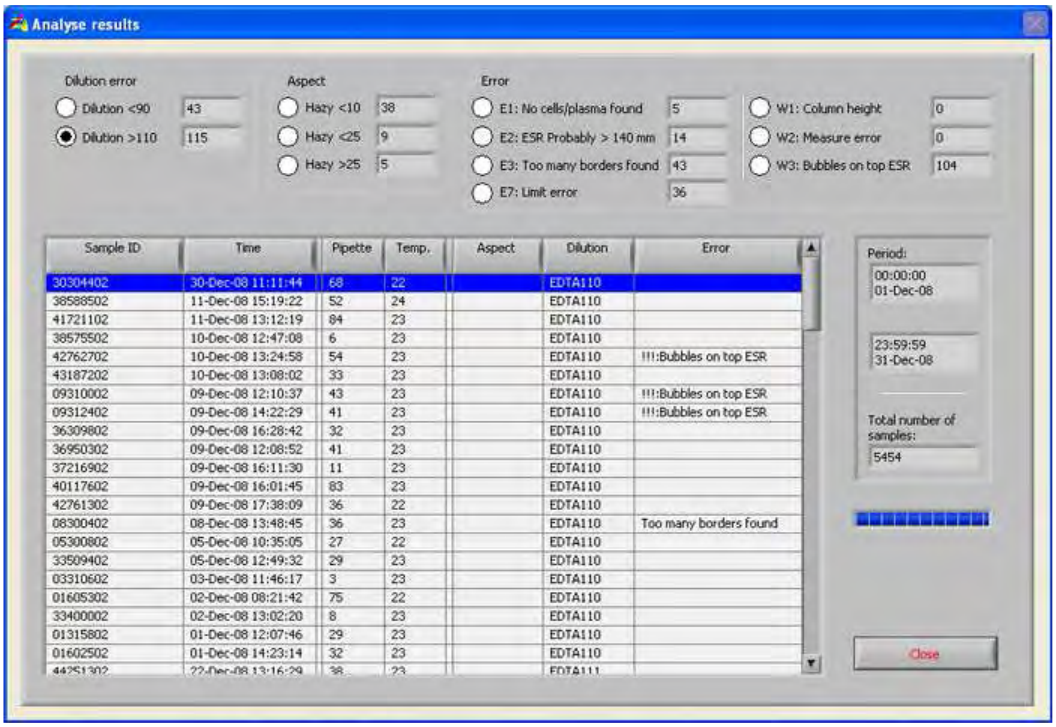
5.3.6. History analyse



DILUTION ERROR
The dilution error detection is a user setting and can be changed in SETTINGS - dilution error detection to 0 ... 25 %. In this example, the dilution error detection is set to 10% and limit errors set to YES.
By selecting Dilution >= 110 all the samples with a dilution rate >= 110 are displayed in the table.
By selecting Dilution <= 90 all the samples with a dilution rate <= 90 are displayed in the table.

In the header of the table the names of the columns are shown. Double-click the header of any column to sort the table by this column in ascending order.

5.3.7. History analyse results high dilution



DILUTION ERROR

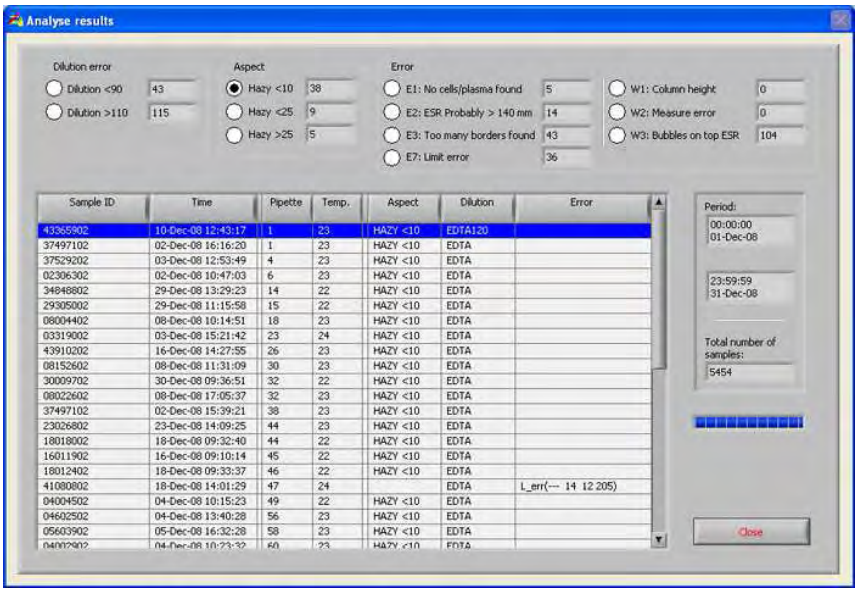
The dilution error detection is a user setting and can be changed in SETTINGS - dilution error detection to 0 ... 25 %. In this example, the dilution error detection is set to 10% and limit errors set to YES.

By selecting Dilution >= 110 all the samples with a dilution rate >= 110 are displayed in the table.

By selecting Dilution <= 90 all the samples with a dilution rate <= 90 are displayed in the table.

In the header of the table the names of the columns are shown. Double-click the header of any column to sort the table by this column in ascending order.

5.3.8. History aspect

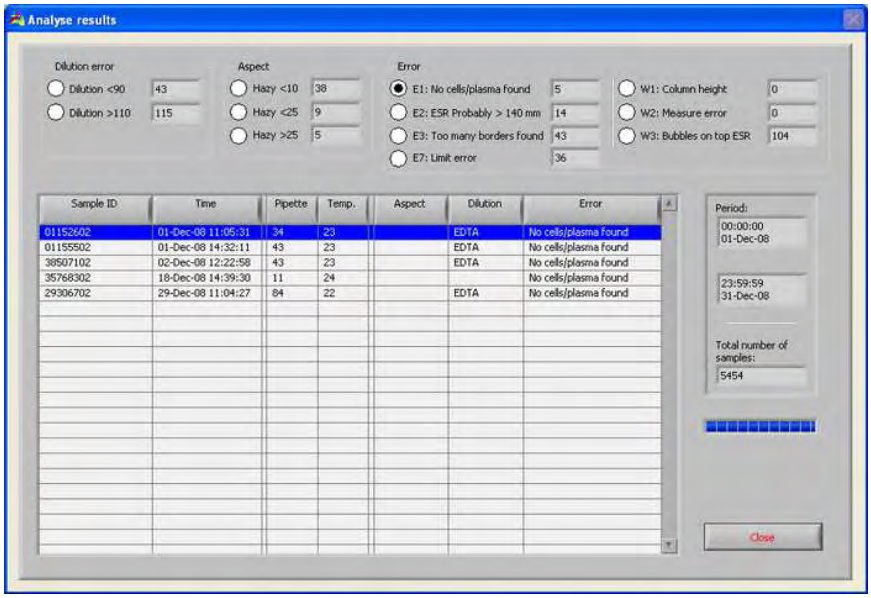


ASPECT

By selecting one of the three Hazy aspect codes, all the samples with this aspect code are displayed in the table, also in case of an error.

In the header of the table the names of the columns are shown. Double-click the header of any column to sort the table by this column in ascending order.

5.3.9. History analyse error

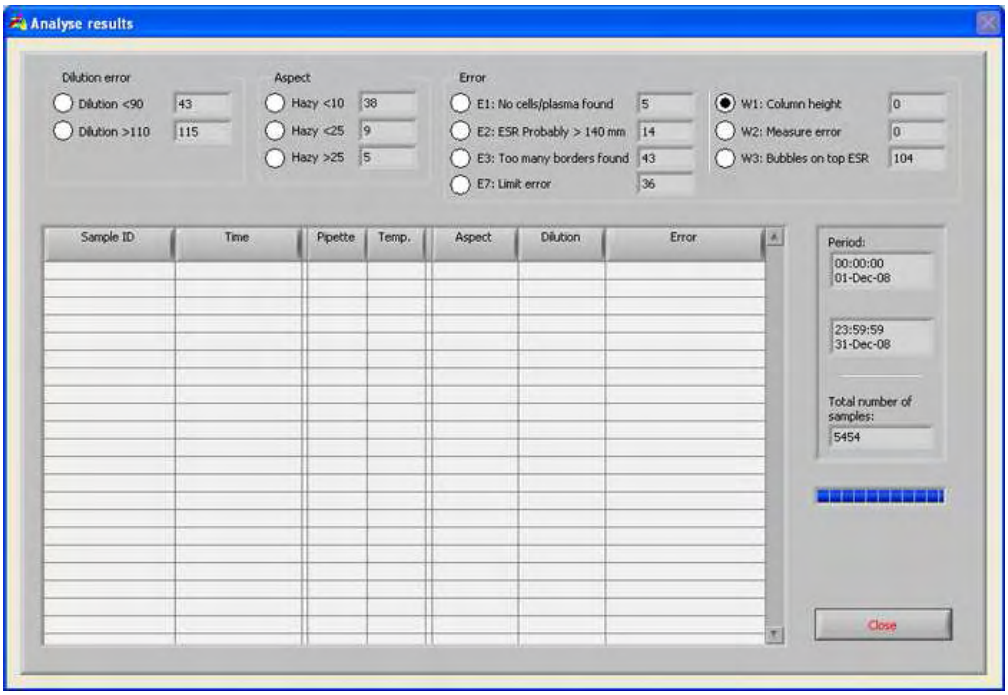


ERROR

By selecting one of the error codes, all the samples with this error code are displayed in the table.

In the header of the table the names of the columns are shown. Double-click the header of any column to sort the table by this column in ascending order.

5.3.10. History analyse warning

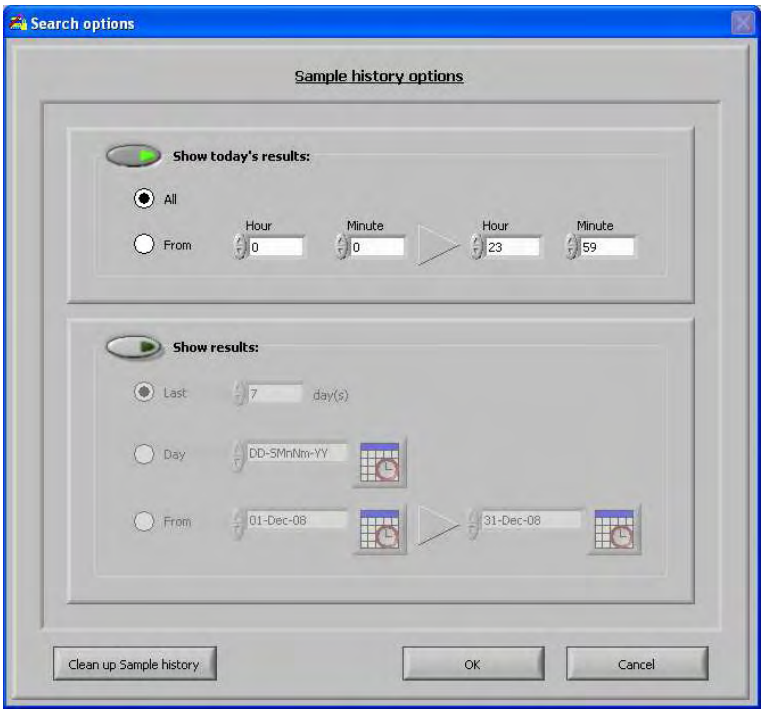


WARNING

By selecting one of the warning codes, all the samples with this warning code are displayed in the table.

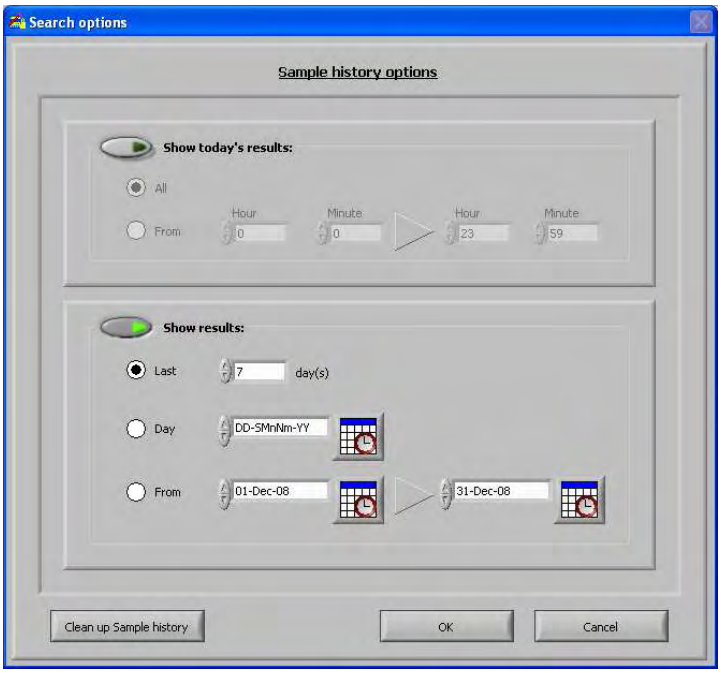
In the header of the table the names of the columns are shown. Double-click the header of any column to sort the table by this column in ascending order.

5.3.11. History sample analyse option day



Make a selection for all of today's results or only today's results between start time and end time.

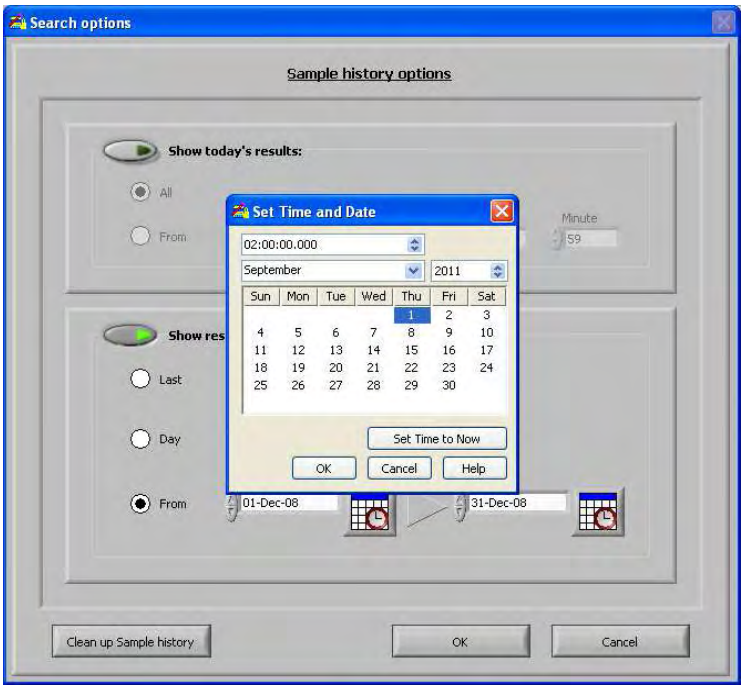
5.3.12. History sample analyse option



Make a selection for

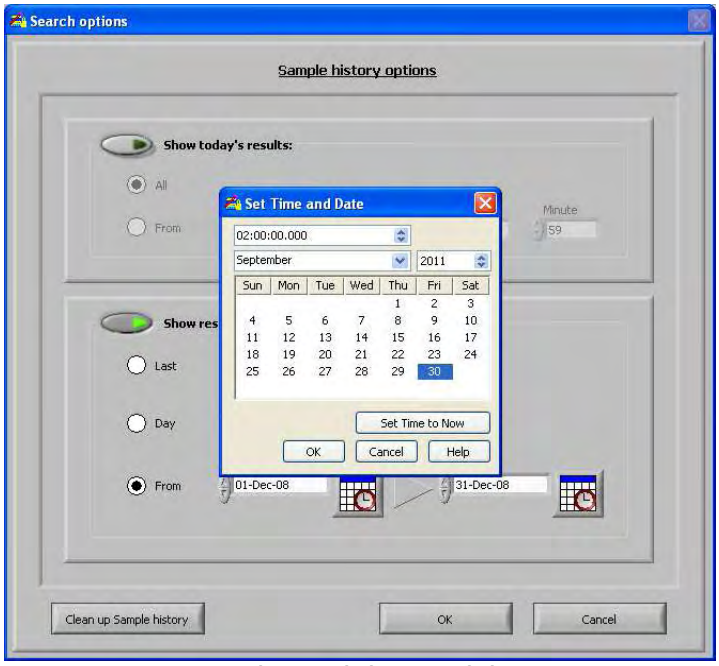
1. A specific number of past days.
2. A specific date.
3. A range of days from start date to end date.

5.3.13. Set start date



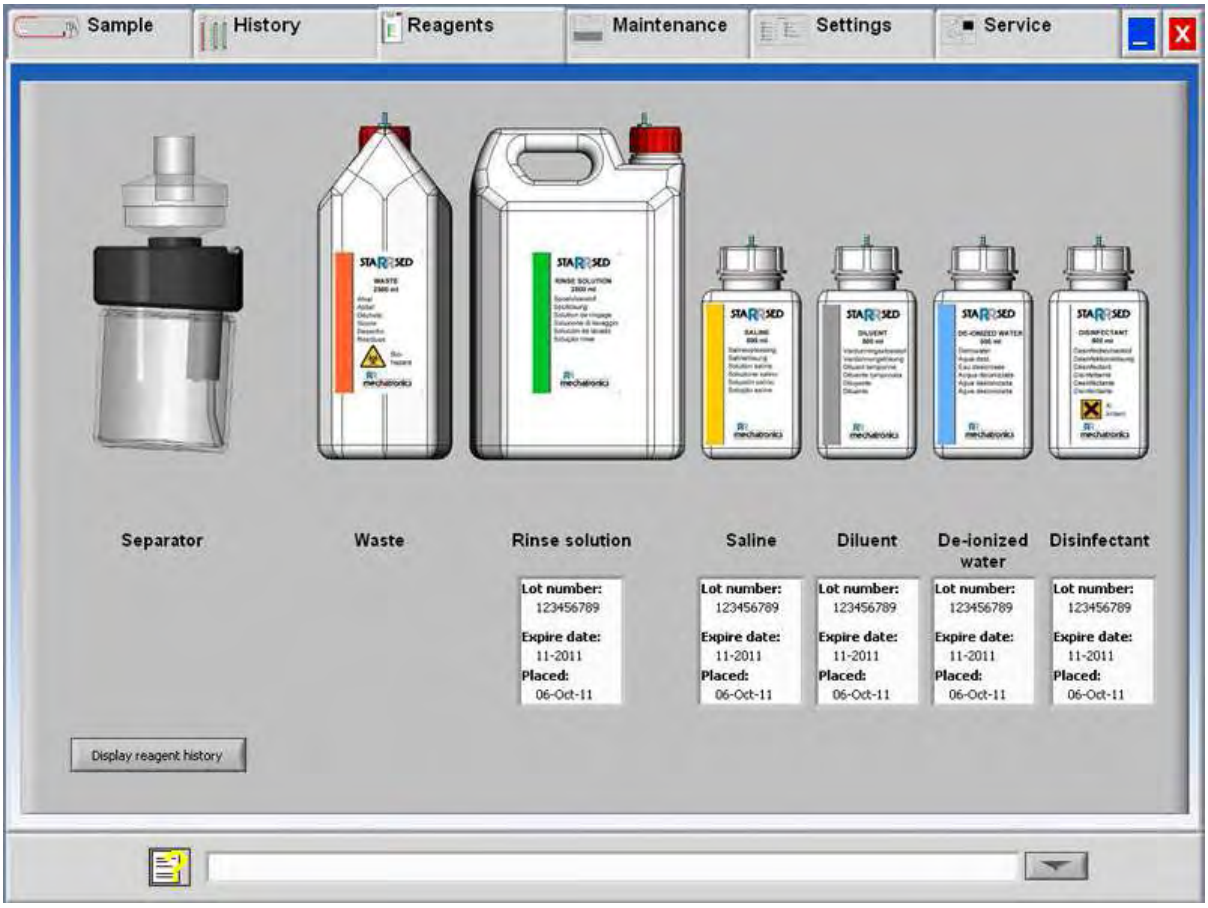
Input the Start date and time.

5.3.14. Set end date



Input the End date and time.

5.4. Reagents screen



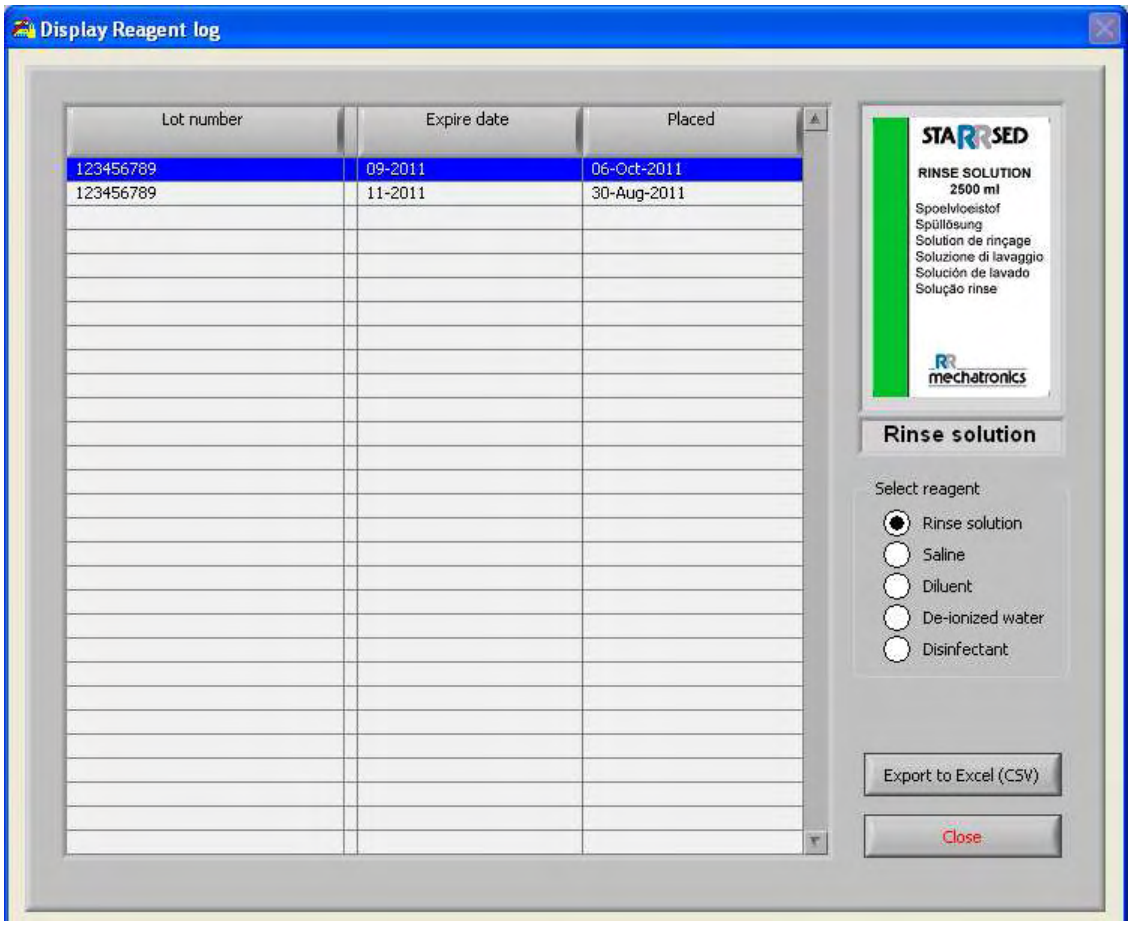
When there is a sensor alarm, an alarm indicator is shown in the tab REAGENTS. The alarm status of the bottles and separator are shown in this screen. An empty bottle is marked by a flashing red to yellow mark.
When the bottle status screen is active, the bottle audio alarm is switched off.
Reagent information is shown in the little text boxes. To input new reagent information when reagent container is replaced, click on the appropriate text box.

Note: When the expire date is exceeded the text box will flash red.

The software checks the bottle status before starting a new rack. If a level alarm is **ON**, it will not process the new rack. If an alarm comes **ON** during a rack, it will finish to aspirate that rack (10 samples max.). Washing dirty pipettes always continues, as to avoid that the samples are left in the pipettes.

Reagents alarm is also set when the expire date of the reagent is exceeded or opened more than three months. The message Not allowed now! See REAGENTS! appears. Processing of new samples is stopped. A log is available for all reagents and can be accessed by clicking on DISPLAY REAGENT HISTORY (on page 48).

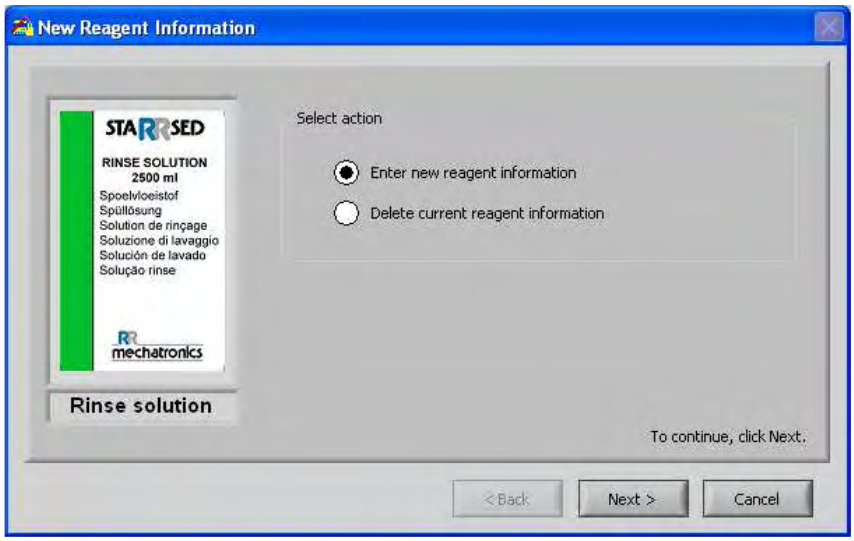
5.4.1. Display reagent history



This screen shows the history of the used reagents.
Select the reagent type on the right side.

For external use of the information all the logged reagent data can by exported to EXCEL .CSV format by clicking Export to Excel (CSV).

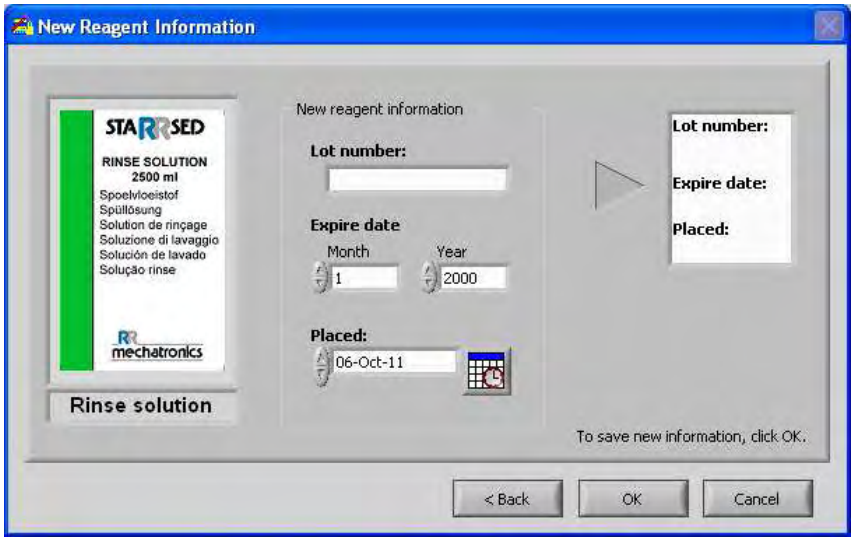
5.4.2. New reagent input



Input screen for new reagents. Make a selection to add new (default setting) or delete the current information and continue with "Next".

Note: Only the Rinse solution input screen is shown in this manual. The input screens are the same for all reagents.

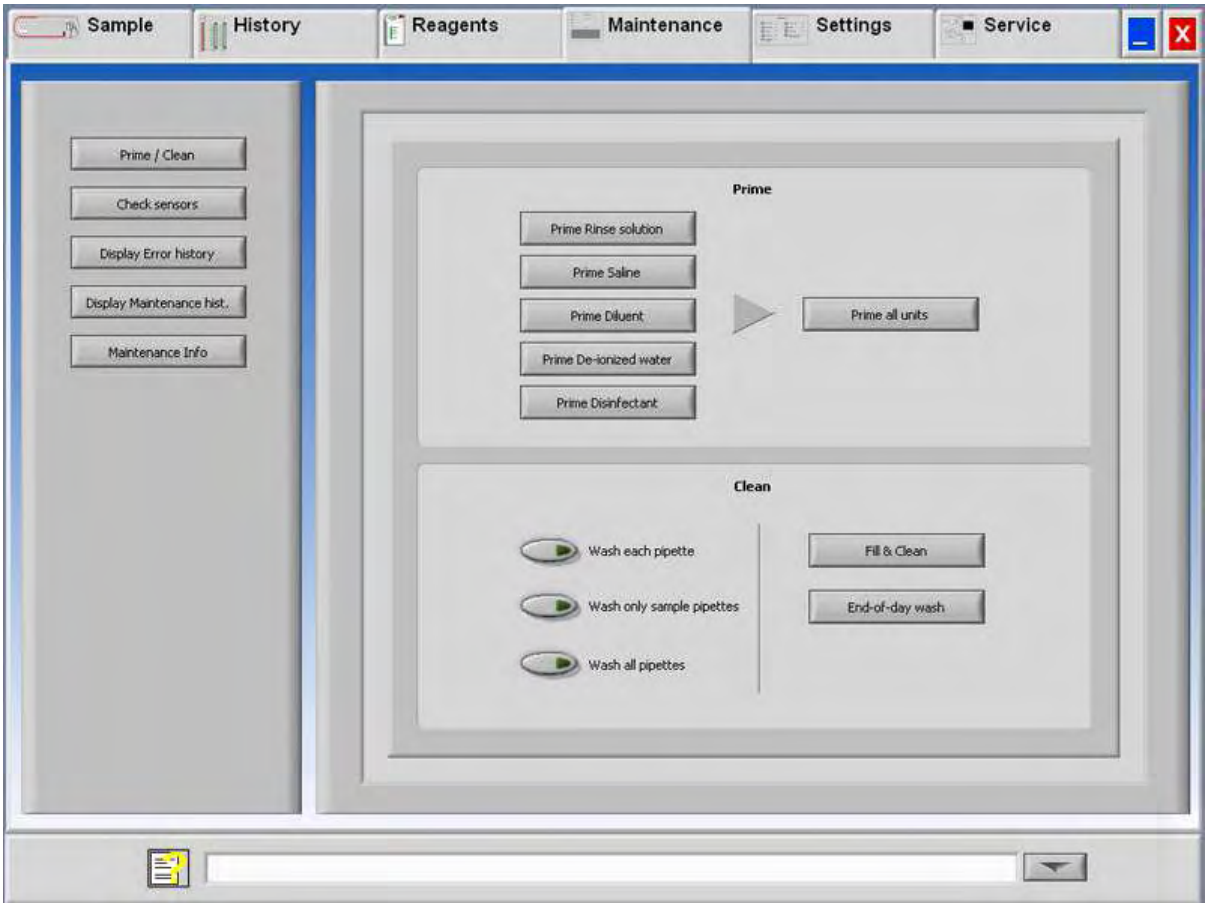
5.4.2.1. New reagent input (cont)



Data can be entered with the keyboard or with a barcode reader.

1. First enter / read the Article number
2. Enter/ read Lot number.
3. Enter / read the Expiry date (if barcode reader is used: cursor has to be in one of the two boxes)
4. If necessary, adjust the date when the reagent was placed.
5. Check if the preview box shows the correct information, then press OK.

5.5. Maintenance screen

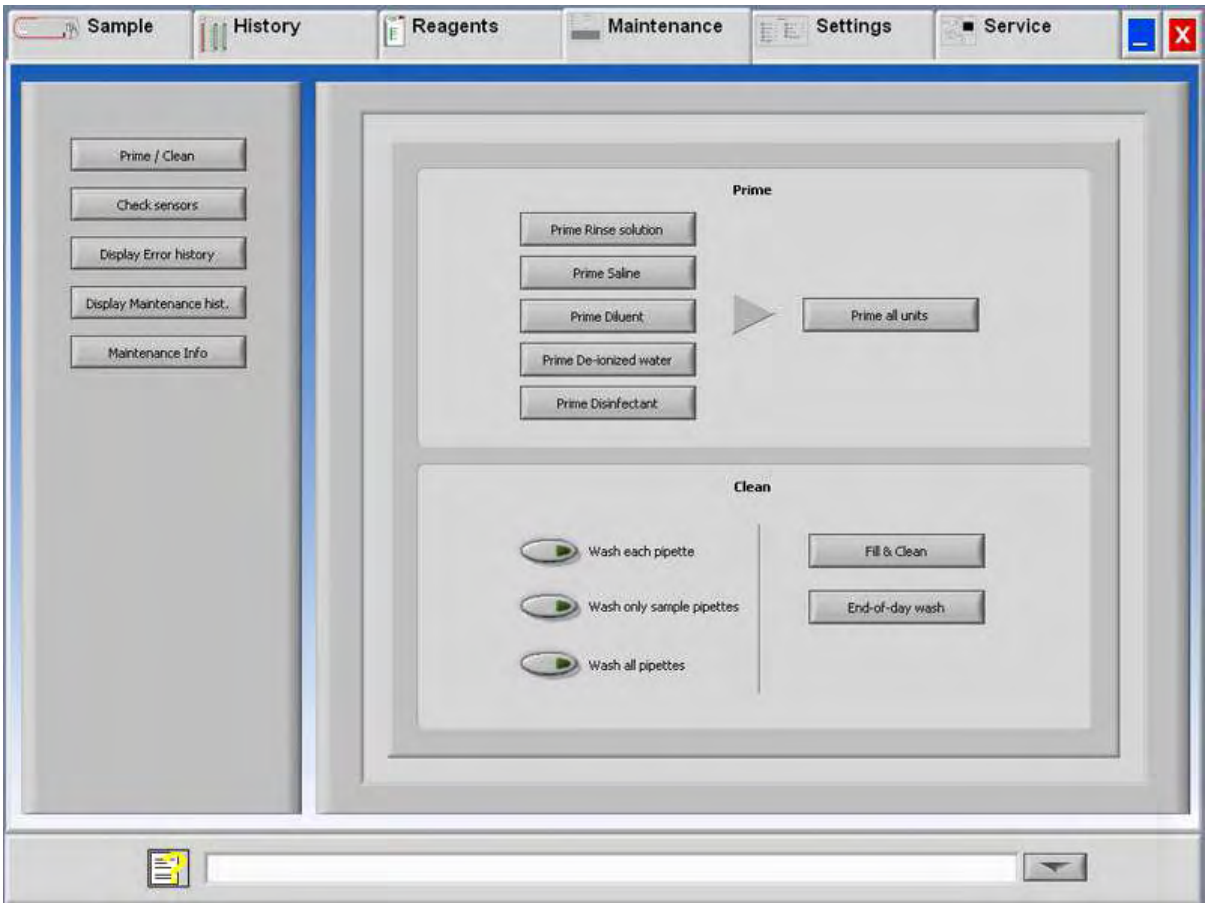


When there is a sensor alarm, an alarm indicator is shown in the tab MAINTENANCE.

This screen has 5 sub screens:

1. PRIME (ON PAGE 51) / CLEAN
2. CHECK SENSORS (on page 54)
3. DISPLAY ERROR HISTORY (on page 56)
4. DISPLAY MAINTENANCE HIST. (on page 57)
5. MAINTENANCE INFO (on page 58)

5.5.1. Prime / Clean



When there is a sensor alarm, an alarm indicator is shown in the tab MAINTENANCE.

All maintenance functions for the fluid system are grouped under button PRIME / CLEAN (on page 51).

After each reagent change, the fluid system must be primed to fill the relevant tubes with reagent and remove air. This is also part of the daily start-up. Use the applicable button to perform the automatic priming cycle for this reagent:

5.5.1.1. Prime Rinse solution

- PRIME RINSE SOLUTION:
  After each measurement, the pipettes are washed and dried automatically.

5.5.1.2. Prime Saline

- PRIME SALINE:
  After each aspiration, the outer needle, sample probe and fill nozzle are washed with saline.

5.5.1.3. Prime Diluent

- PRIME DILUENT:
  The Diluter prime cycle is 5 strokes of the syringe.

5.5.1.4. Prime de-ionized water

- PRIME DE-IONIZED WATER:
  After each aspiration, the fill nozzle is flushed with de-ionized water.

5.5.1.5. Prime Disinfectant

- PRIME DISINFECTANT:
  During a pipette rinse cycle, a small amount of disinfectant is flushed around the bottom of the pipette and into the waste system.

5.5.1.6. Prime all units

When the StaRRsed Auto-Compact has been idle for more than eight hours, some reagents may have dropped from the tubes due to gravity. Prime all tubing before sampling with:

- PRIME ALL UNITS
  All priming functions are sequentially performed one time.

5.5.1.7. Wash each pipette

- Wash each pipette:
  When the pipette belt turns one position, the pipette at the rinse position will be rinsed and dried, regardless if it was filled or not.

5.5.1.8. Wash only sample pipettes

- Wash only sample pipettes:
  All pipettes which are currently holding samples are washed and dried ones.
  A warning is shown on the display: <Pipette data will be lost!>.

  NOTE: Before executing this function, check carefully if there are samples in the pipette belt that need to be measured.
  Any remaining samples will be washed away and will **NOT** be measured!

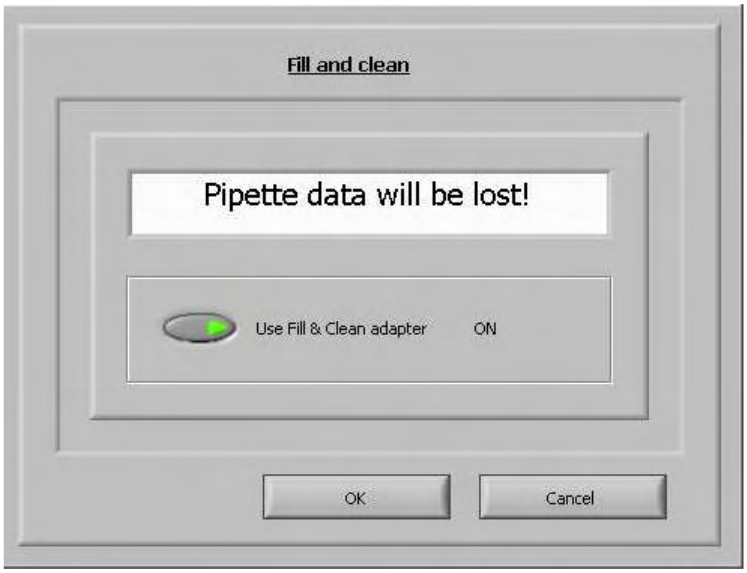
5.5.1.9. Wash all pipettes

- Wash all pipettes:
  All pipettes on the pipette belt are washed and dried ones.
  A warning is shown on the display: <Pipette data will be lost!>.

  NOTE: Before executing this function, check carefully if there are samples in the pipette belt that need to be measured.
  Any remaining samples will be washed away and will **NOT** be measured!

5.5.1.10.Fill and clean screen

Fill & Clean:
Automatic fill and clean function, each individual pipette on pipette belt will be filled with cleaning solution. During prolonged use of the instrument, proteins are building up in the Westergren pipettes which need to be removed using a strong cleaning agent.
This cycle takes about 90 minutes.
The Fill & Clean function is part of the monthly maintenance procedure.
A warning is shown on the display: <Pipette data will be lost!>.



By toggling the switch ON the Fill and clean adapter is used.

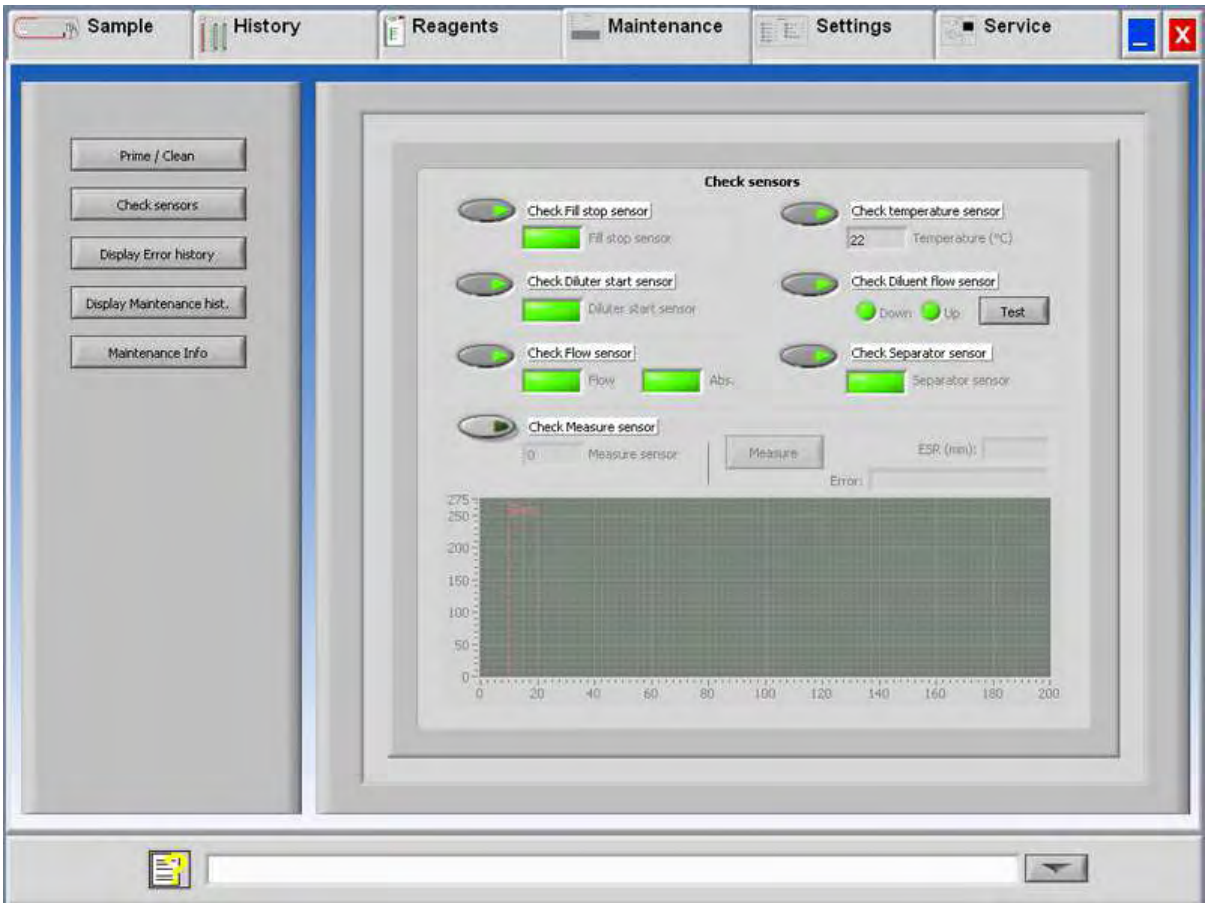
By toggling the switch OFF the Fill and clean without adapter is used.

See chapter Maintenance ***Fill and clean procedure*** (on page 93) for more information.

5.5.1.11.End-of-day-wash procedure

- End-of-day wash:
  All pipettes will be washed once and needle, fill-nozzle and rinse-nozzle (wash station) are primed.

5.5.2. Check sensors



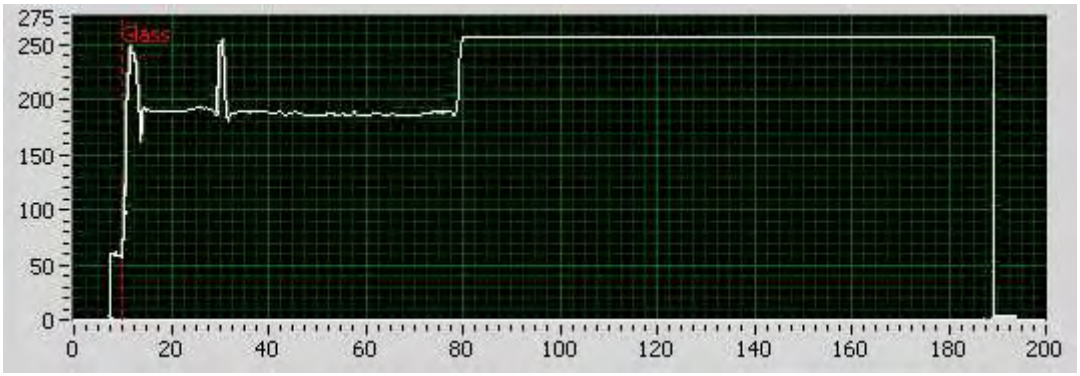
When there is a sensor alarm, an alarm indicator is shown in the tab MAINTENANCE.

All functions to check the status of the sensors are grouped under button CHECK SENSORS (on page 54).

- Check Fill stop sensor: Click the Check button. The green light is shown if the sensor value is in range.
- Check temperature sensor: Value must be equal to the actual room temperature near the pipette belt.
  The value can be set in tab SETTINGS.
- Check Diluter start sensor: This sensor is only used in EDTA mode. If the diluter does not start during the aspiration, the status of this sensor must be checked.
  Click the Check button. The green light is shown if the sensor value is in range.
- Check Diluent flow sensor: This sensor is only used in EDTA mode. When activated, the LED Down is green and the LED Up is red. When the button Test is clicked, the LED Up must become green. After finishing the test, both LED's must be green.
- Check Separator sensor: Click the Check button. The green light is shown if the sensor value is in range.

- Check Flow sensor: Click the Check button. The green light is shown if the sensor value is in range.
- Check Measure sensor: Click the Check button. The green light is shown if the sensor value is in range.
  Press the button MEASURE. The pipette currently at the measure position will be measured.
  The results are displayed in graphical form:

Measure head start position correct



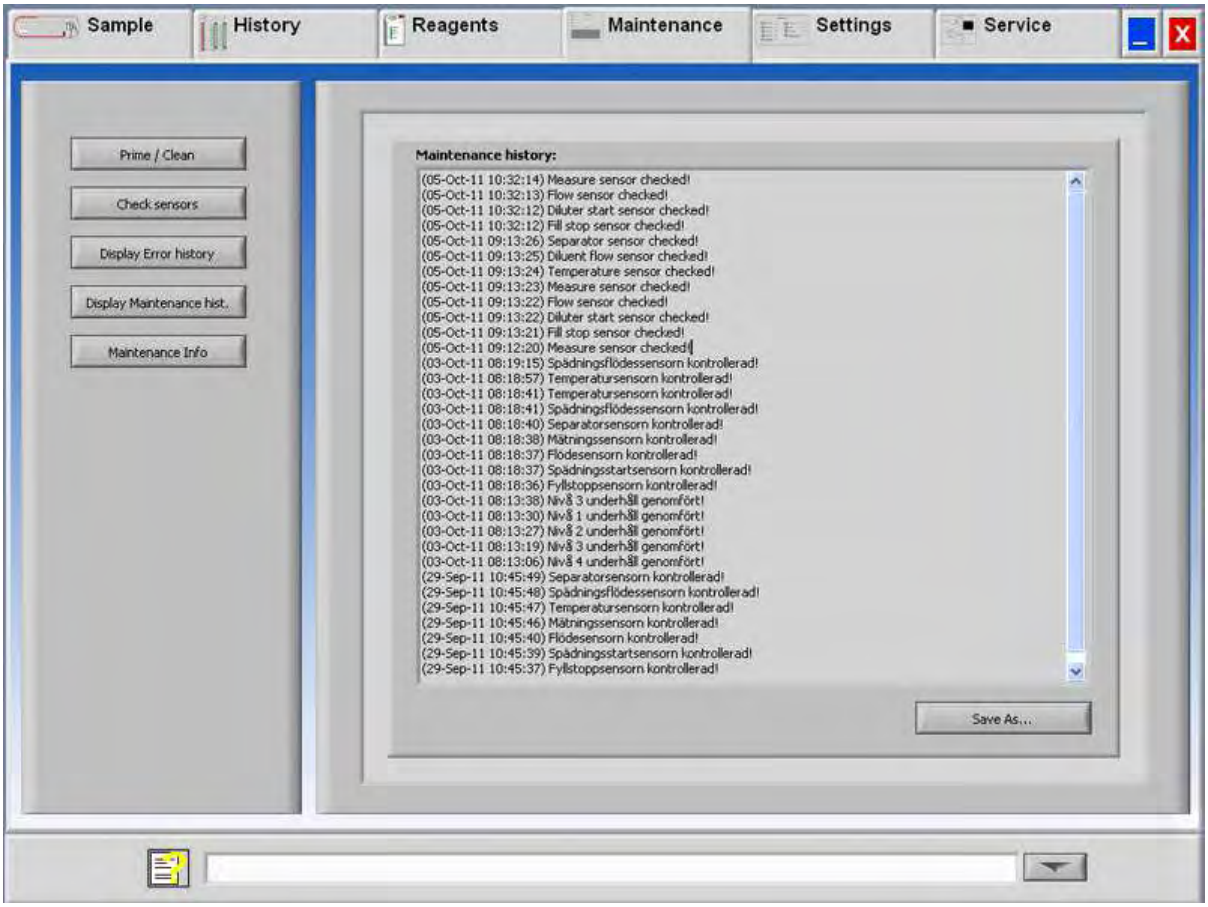
Measure head start position wrong

NOTE: Clean sensors first before executing this function.

NOTE: When a test pipette is installed at the measuring position the result of the test pipette is displayed in the field "ESR (mm)".

Note: When the sensor is out of range and the light is red, the sensor values can be checked by turning on the service mode.

5.5.3. Display error history

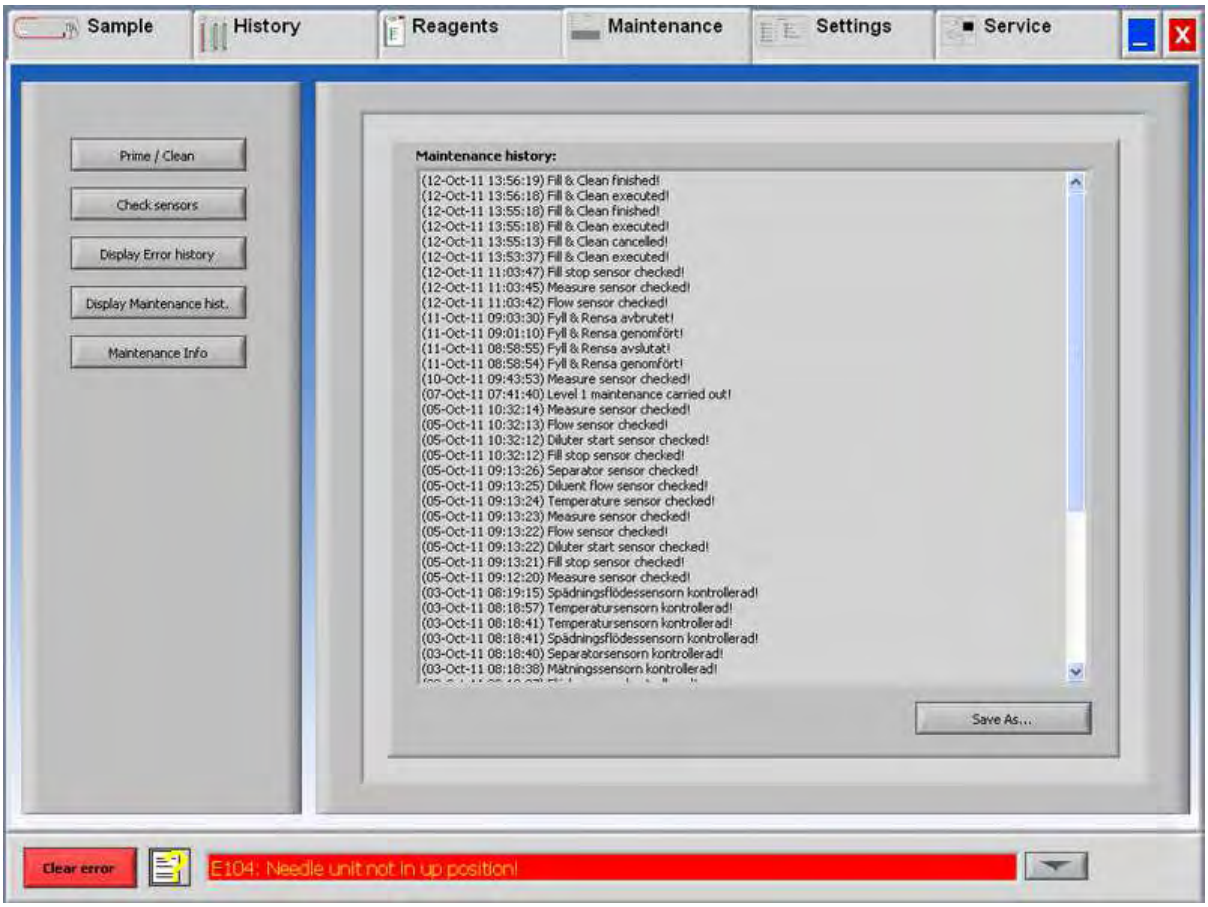


When there is a sensor alarm, an alarm indicator is shown in the tab MAINTENANCE.

All errors that occurred during operation are logged automatically.
This list can be used by field engineers to check check the status of the instrument and locate possible problems.

This log can be saved e.g. to a memory stick by clicking button **Save As ...**

5.5.4. Display maintenance history

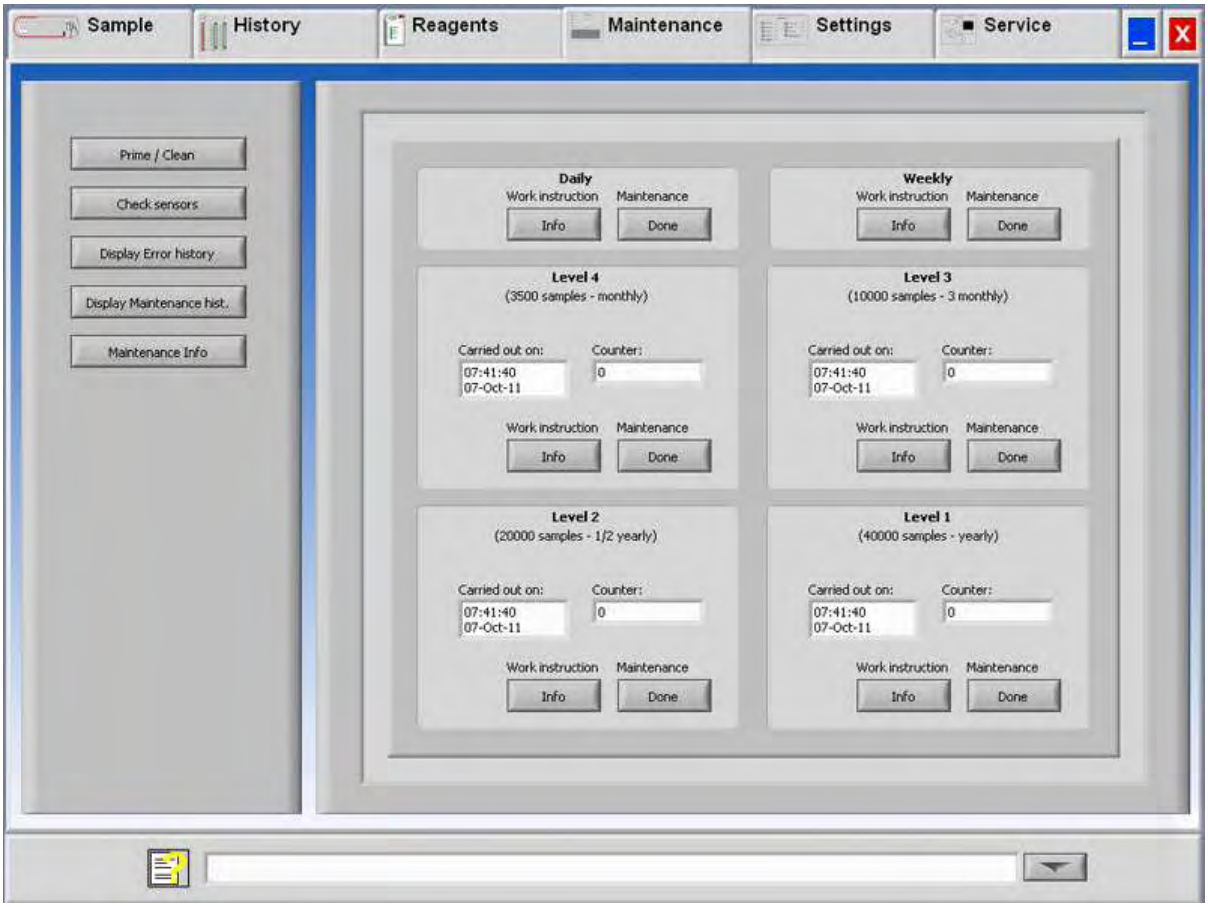


When there is a sensor alarm, an alarm indicator is shown in the tab MAINTENANCE.

All performed maintenance functions are logged automatically.

This log can be saved e.g. to a memory stick by clicking button **Save As ...**

5.5.5. Maintenance info



When there is a sensor alarm, an alarm indicator is shown in the tab MAINTENANCE.

This screen is divided in 6 maintenance level sections. For maintenance levels 1 to 4, the status is monitored and flagged if it is overdue.

Press the button **Info** to open the work instruction for a specific maintenance level.

When this maintenance is done press the button **Done** to log the completed work in the maintenance log file.

5.5.5.1. Maintenance info overview

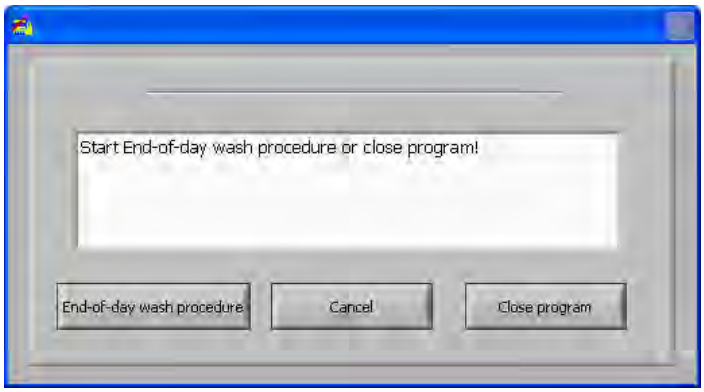
When there is a sensor alarm, an alarm indicator is shown in the tab MAINTENANCE.

This screen is divided in 6 maintenance level sections. For maintenance levels 1 to 4, the status is monitored and flagged if it is overdue.

Press the button **Info** to open the work instruction for a specific maintenance level.

When this maintenance is done press the button **Done** to log the completed work in the maintenance log file.

5.5.6. Close



Make the selection End-of-day wash procedure or Close program:

End-of-day wash procedure will start to wash all pipettes, needle, fill-nozzle and rinse-nozzle (wash station). The function can be set up for automatic execution in the following screen.

Close program will only close down the program.

5.5.7. End-of-day-wash options

End-of-day wash procedure:
All pipettes will be washed once, needle, fill-nozzle and rinse-nozzle (wash station) are primed.

The following settings can be selected for the function:

- No End-of-day wash: The function is not active.
- Immediately: The function runs immediately after pressing the button OK.
- Only once: The function runs only once at the selected time.
- Weekdays: The function runs only on working days (monday till friday) at the selected time.
- Daily: The function runs on a daily base at the selected time.

5.5.8. End-of-day-wash schedule settings

End-of-day wash procedure:
All pipettes will be washed once, needle, fill-nozzle and rinse-nozzle (wash station) are primed.

Select the time of the day in hours and minutes for automatic start of this function.

5.6. Settings screen

The SETTINGS screen is for specially trained supervisors and engineers and outside the scope of the Instructions For Use.

5.7. Service screen

The SERVICE screen is for specially trained engineers and outside the scope of the Instruction For Use.

6. REPORTING

The StaRRsed Auto-Compact is able to handle different types of protocols. The selection is made in SERVICE - SERIAL OUTPUT SETTING.

6.1. Protocols

A protocol is a set of rules governing the communication and the transfer of data between machines, as in a computer system. It is also a formal set of rules and procedures to be followed during a request for information before data is transferred between machines and computer systems.
The following protocols can be selected for data transfer to the Laboratory data processor computer.

1. No Serial output
2. MECHATRONICS-01 bidirectional
3. MECHATRONICS-02 unidirectional
4. Sysmex SE 9000
5. Sysmex SE-9000 unidirectional
6. Sysmex R-3500
7. Sysmex R-3500 unidirectional
8. Compact bidirectional
9. Compact unidirectional (String format for StaRRsed)
10. StaRRsed III (V14)
11. Vesmatic
12. Sedimatic 15
13. Sedimatic 100
14. Opus bidirectional
15. Advia 120 bidirectional
16. Advia 120 unidirectional

The protocol can be set in tab SERVICE - Serial output settings. After selecting a protocol, save the new settings by pressing the Save setting key.

6.2. Result Printout

The results of the ESR measurements are send to the printer. The layout of the report depends on the selection of the 60- or 30 minute method.

6.2.1. Report 60-Minute mode

Colums:

1. Patient number.
2. Not corrected 30-minute ESR result (only in use if 30 minute mode is active).
3. Not corrected 60-minute ESR result.
4. 60-minute ESR result in millimeters, corrected for **18**℃. (only in use if temperature correction is active).
5. Aspect (clear, hazy).
6. Manually entered code number.
7. Sedimentation pipette number (number on the pipette belt).
8. Actual sedimentation time in minutes.
9. Temperature (in degrees Centigrade).
10. Error message (if the Analyser detects an error).
11. EDTA mode.

+ REPORT EXAMPLE +(Not to scale)

-- StaRRsed-- Date 20/05/14 Time: 15:28

1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*
905001		84	75	CLEAR		17	60	23		EDTA
905002		14	13	Hazy<10mm		18	60	23		EDTA
905003		22	21	Hazy<25mm		19	60	23		EDTA
905004		67	61	Hazy>25mm		20	60	23		EDTA
905005				CLEAR	**3**	21	60	23		EDTA
905006		5	5	CLEAR		22	60	23		**EDTA 079**
905007						24	60	23	Too many borders found	
905008						25	60	23	**L_err(---/ 84/ 75/200)**	EDTA

905002/905003/905004
Sample results with hazy aspect

905005:
Sample result with a manual aspect, where the manual aspect is shown as a number **3** in column 6 of this data record sample.

905006:
In this sample, the dilution rate has a dilution failure of 21% and that is printed as **EDTA 079.**

905007
Sample results with a text error. This sample gives Too many borders found. Result of a pipette possibly filled with air bubbles.

905008
Sample result with a text error. This sample is given limit error L_err(---/ 84/ 75/200)

6.2.2. Report 30 Minute mode

Columns:

1. Patient number.
2. Not corrected 30-minute ESR result (only in use if 30 minute mode is active).
3. Not corrected 60-minute ESR result.
4. 60-minute ESR result in millimeters, corrected for **18**℃. (only in use if temperature correction is active).
5. Aspect (clear, hazy).
6. Manually entered code number.
7. Sedimentation pipette number (number on the pipette belt).
8. Actual sedimentation time in minutes.
9. Temperature (in degrees Centigrade).
10. Error message (if the Analyser detects an error).
11. EDTA mode.

+ REPORT EXAMPLE +(Not to scale)

- StaRRsed-- Date 20/05/14 Time: 15:28

1	2	3	4	5	6	7	8	9	10	11
915001	42	84	75	CLEAR		17	30	23		EDTA

6.2.3. ESR Error

Error messages can be found on the printout in column 10.
If errors are found during the measurement, the Compact will give an audible alarm.
The Error message is displayed on the main screen.

6.2.3.1. ESR Error and Warning code messages

ESR "ERROR" and "WARNING" code messages

This code appears in the "sample data record" at column 10.
The following codes are defined:

0	No errors		
1	No cells/plasma found	Error	No contents could be detected in the pipette.
2	ESR Probably > 140 mm	Error	Extremely high ESR value.
3	Too many borders found	Error	More than three borders found, possibly air bubbles. See Section Trouble shooting ***Air bubbles*** (on page 82).
4	Column height <nnn>	Warning	Column height must be between 180 and 210mm. <nnn> = the actual column height.
5	Measure error	Warning	The down count is not equal to the up count from the measure head.
6	Bubbles on top	Warning	Air bubbles on top of the ESR. See Section Trouble shooting ***Air bubbles*** (on page 82).
7	Limit error	Error	One of the following limits are out of the setting range: • ESR Time • Column height • Dilution • Bubbles on top • Hazy aspect • Temperature

6.2.4. Limit error settings

When an option (at Limit error settings) is set to YES and this limit error occurs, results will be printed/send to the LIMS.

When an option is set to NO and this limit error occurs, the fields for *30 min ESR, 60 min ESR* and the *temperature corrected ESR* are filled with spaces and thus results are not printed/send to the LIMS.

The error message in the error field (column 10) indicates that at least one of the limits (ESR time, dilution rate, column height, bubbles on top, hazy aspects and temperature) has been exceeded.

Together with the sedimentation time and dilution rate (which are still printed at the usual position), the operator/analyst can see what caused the error and may or may not use the ESR values which are preserved in the error message.

Description of the error message **L_err(hhh/www/ttt/ccc)** :

- **L_err** means it is a "limit error"
- **hhh** is the 30 minutes ESR
- **www** is the 60 minute ESR
- **ttt** is the temperature corrected 60 minute result
- **ccc** is the column height

Example of a limit error message:

- L_err(42/ 84/ 75/200) means 42 mm in the 30 minute method and temperature correction 75 with a correct column height.
- L_err(---/ 84/ 75/200) means 84 mm in the 60 minute method and temperature correction 75 with a correct column height.

6.2.5. Reporting range

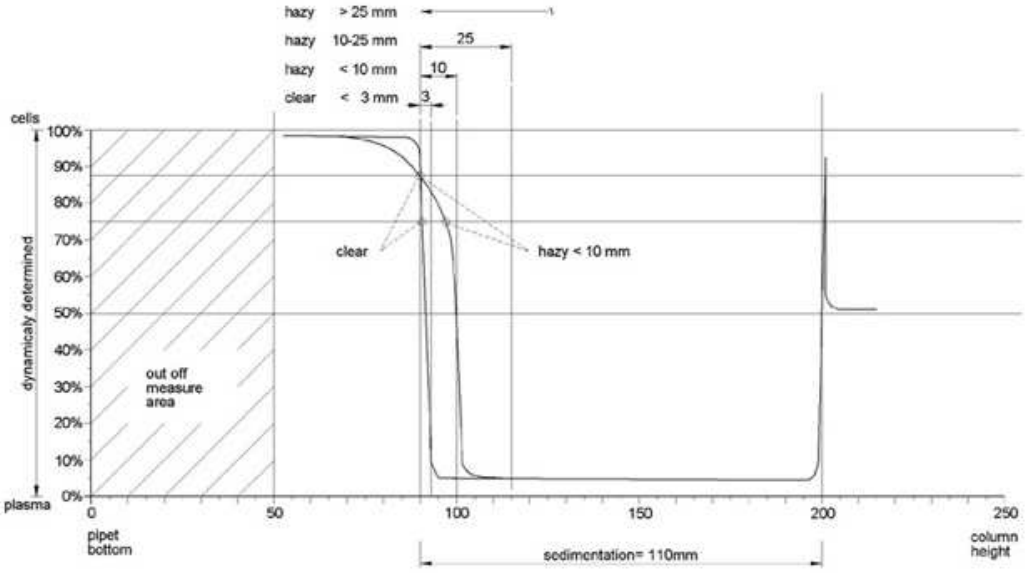
The reporting range in the columns 2, 3 and 4 are in millimeters. The start of the measure range is at the top of the meniscus down to 140 mm. If the detection of cells/plasma is over 140 mm then the report will be >140.

6.2.6. Aspect Hazy

The automatic reading of the Westergren sedimentation pipettes is carried out by moving an optical sensor along the pipettes. While the sensor is moving, a reading is made every 0.25 mm. The sensor is reading the absorption of infra red light through the Westergren pipette filled with blood. From these readings, values at a number of absorption levels are determined. All absorption figures are relative to the darkest and lightest reading (darkest = 100 % and the lightest = 0 % absorption respectively).

By definition the levels are:

87.5%	Cells/ plasma separation
75.0%	Hazy detection
50.0%	Meniscus detection



Graphic showing typical absorption values of a sample

The 'sedimentation' value is the distance in millimeters between the cells/plasma level (87.5% absorption) and the meniscus. If there is no haze, the absorption drops quickly to a value below the 75% level. If the distance between the 87.5% and the 75% level is less then 3mm, the report will state 'CLEAR'. If the distance between 87.5% and 75% level is more than 3mm then the report will state 'HAZY'.

Depending on the length of the 'hazy' area, three classes of 'haziness' are reported,

Length of area		**Reported class**	
Hazy area	>25 mm	Hazy	>25 mm
Hazy area	>10 mm <25 mm	Hazy	<25 mm
Hazy area	>3 mm < 10 mm	Hazy	<10 mm
Hazy area	< 3 mm	CLEAR	<3 mm

Hazy reports are shown when the change from the hazy level to the cell/plasma separation level occurs not within a given distance. The following code messages are reported in column 5.

6.2.6.1. Analyser "HAZY" code messages

This code appears in the "sample data record" at column 5.

The following 4 codes are defined:

0	Sample is clear.
1	Sample is Hazy < 10
2	Sample is Hazy < 25
3	Sample is Hazy > 25

Results with hazy aspect can be suppressed in the menu Limit error settings.

7. OPERATION

7.1. Quick start-up

This section describes a quick start-up procedure and a general description of what to do before starting a large batch of samples to run through the system.

7.1.1. Check list

Run this checklist before each large batch of samples.

1. Waste container (if applicable), should be empty.
2. Check the liquid levels.

7.1.2. Power up sequence

Switch ON procedure:

- Switch **ON** the Compact.
- Switch **ON** the PC and monitor.
- Wait until "Windows" is ready for use.
- Start the Compact software.

7.1.3. Priming the fluid system

Select MAINTENANCE -> PRIME / CLEAN (on page 51) and perform all prime sequences manually. Check fluid flow through the applicable tubing. repeat a step if fluid flow is not correct.

1. PRIME RINSE SOLUTION, activates the Rinse pump. RINSE SOLUTION must flow through the pipette.
2. PRIME SALINE, activates the SALINE pump. Liquid must flush through the needle assembly.
3. PRIME DILUENT, activates the diluter prime cycle. Diluter system must be filled with diluent and free of air bubbles.
   - Diluter prime cycle is executed once. In order to fully prime the system it will be necessary to perform this step several times. (One cycle is 5 strokes of the Diluter)
4. PRIME DE-IONIZED WATER, activates the fill nozzle water valve. DE-IONIZED WATER must flow through the tube connected to the fill nozzle cap.
5. PRIME DISINFECTANT, activates the disinfectant valve. Disinfectant must flow through the small tube connected to the pipette wash station.

When the StaRRsed Auto-Compact has been idle for more than eight hours, some reagents may have dropped from the tubes due to gravity. Prime all tubing before sampling with:

- PRIME ALL UNITS
  All priming functions are sequentially performed one time.

7.2. Fill procedure

Fill the sample rack with the sample tubes. Observe that the barcodes are visible through the opening in the rack. Place the rack in a rack adapter.

Set the Rack adapter in the rack loader with the barcodes facing the rack grabber. Select the tab SAMPLE and press the button Sample mode.
The Rack is transported to the rack grabber, the rack grabber picks up the Rack adapter and moves to the barcode reader position to scan the first barcode label. The rack is then mixed and after that moved to the needle position to be aspirated.

If the barcode labels fail to read check if the barcode is facing the correct direction.

Note: BE SURE THAT THE COMPACT IS SET TO THE CORRECT MODE. i.e. EDTA or CITRATE.

7.2.1. Liquid levels

Liquid containers and levels must be checked frequently.
If the small onboard bottles are used, wash and keep the bottles clean to avoid bacterial growth.

The StaRRsed Auto-Compact has liquid level sensors. When the level sensor alarm appears, replace reagent as soon as possible.

7.3. Checks during operation

- Perform regularly visual checks for air bubbles in the sample pipettes, see ***Air bubbles*** (on page 82).
- Check regularly the ESR statistics in the software for any increase in ESR errors, haziness, dilution errors or bubbles on top warnings, see ***ESR Statistics screens*** (on page 31).

In case of a considerable number of pipettes with air bubbles:

- Perform the necessary maintenance or contact the service representative.

7.4. Turn off

It is recommended to turn the StaRRsed Auto-Compact off at the end of the day. Before the instrument is turned off, it is good practice to carry out the ***Daily maintenance*** (on page 88) or at least the End-of-day wash procedure. This will help to keep the instrument clean and almost free of bacterial growth for a period of days.

W A R N I N G!!!
Always be aware of the dangers of infection, especially during maintenance. Take the appropriate precautions.

Note: The StaRRsed Auto-Compact may remain switched ON continuously. However, the customer should consider environmental issues such as energy consumption when the instrument is not to be used for some time. It is also recommended to completely restart the instrument and (if applicable) Windows once in a while to clear the memory and ensure a stable operating system.

7.4.1. End-of-day-wash procedure

Select the tab MAINTENANCE and press the button End-of-day wash. A pop-up screen is shown. Selecting Close program will stop the program immediately **without** running the End-of-day wash procedure.
When End-of-day wash procedure is selected, a selection screen for this function is shown.

The following options are available for this function:

1. Select from the list the desired option:
   - No End-of-day wash!: The function is not active
   - Immediately: The function runs immediately after pressing **OK**.
   - Only once: The function runs only once at the selected time.
   - Weekdays: The function runs only on the working days (Mo-Fr) at the selected time.
   - Daily: The function runs on a daily base at the selected time.
2. Select the time of the day in hours and minutes for the selected option.

Pressing **OK** activates the settings.

7.4.2. Turn off sequence

- Close the StaRRsed Auto-Compact software.
- Switch the PC and monitor **OFF**.
- Switch (optional) printer **OFF.**
- Switch the Compact **OFF**.

8. QUALITY CONTROL

8.1. Control pipettes

The correct function of the hardware and software of the StaRRsed Auto-Compact measurement unit should be checked at regular intervals with the aid of Mechatronics Control Pipettes (Order nr. QTST049000). More information can be found in the Control Pipette User Manual (MRN-019).

8.2. Monitoring measurement quality with StaRRsed Control

StaRRsed Control is an in-vitro diagnostic quality control material to monitor the accuracy and precision of Erythrocyte Sedimentation Rate (ESR) instruments and procedures. This instruction is only applicable for StaRRsed Control, used on Mechatronics ESR StaRRsed instruments.

StaRRsed Control is available in:

- Abnormal range (Level A)

- Normal range (Level N)

The software can produce statistical data for further analysis for:

- Defining control limits (accept or reject patient results)
- Error detecting (systematic or random errors)
- Evaluation of QC results

8.2.1. Limitations

StaRRsed Control is to be used for Erythrocyte Sedimentation Rate testing only and shall not be used to control any other hematology procedure.
StaRRsed Control shall not be used as a standard.
StaRRsed Control should not be used past the expiration date.
Mechatronics as supplier of the StaRRsed Control shall not be liable for any claimed damages arising from other than intended usage.

8.2.2. Expected value range

StaRRsed Control is assayed for the StaRRsed ESR analyzers.
The assayed mean values and expected ranges are derived from multiple analyses at different sites and on multiple instruments. The values, provided on the package insert and encoded in the tubes barcode, are specific for this lot of product. The lab should establish its own acceptable ranges. Whenever the Controls fail to perform consistently within the acceptable ranges, patient results should be considered invalid. Contact your StaRRsed instrument provider for assistance. If results vary outside the specified assay ranges, discard the tube and utilize a new tube. If difficulties persist, contact your supplier for further assistance and/or instructions.

8.2.3. Temperature correction

The assayed values are based on an 60 minutes ESR, with dilution and temperature correction. Therefore, the measured ESR value should be compared with the expected value *using temperature correction*. The calculation of a 30 minute measurement to a 60 minute ESR result with temperature correction influences the QC result.

See chapter ***QC Results*** (on page 74) for more information.

8.2.4. Usage options

StaRRsed Control can be used in two ways:

1. With original StaRRsed barcode label:
   The StaRRsed software maintains internal QC history and sends an error message when test results are out of range.
2. With user barcode label:
   The user can use his own ID labels (hereafter called "Lab ID"). Existing QC procedures and LIMS interface settings can be maintained without any changes. The Lab ID is linked within the StaRRsed software to the original StaRRsed Control barcode.
   An external barcode reader can be used to read the 10-character QC barcode labels on the tube or the package insert to create the link. The barcode symbology is "Code 39".

When StaRRsed Control label or a linked user barcode label is used:

- The StaRRsed software recognises the StaRRsed Control sample by the structure of the barcode, which contains the following information: Level A or N, the expected mean value and range and the expiry date.
- The history of QC results is maintained internally. Error messages are generated when the QC results are outside the acceptable range.
- QC samples can be optionally requested by the LIMS and QC results can be send to the LIMS.

StaRRsed Control can be used on StaRRsed analysers in EDTA or in Citrate mode. Quality Control sampling can be performed at any time during the normal ESR procedure, depending on users Quality Control schedule.

Quality Control scheduling is the responsibility of the user. The StaRRsed software does not provide Quality Control scheduling functionality.

8.2.5. Quality control procedure

StaRRsed Control is provided in ready-to-use sample tubes and is used in the same manner as patient samples. StaRRsed Control is to be used for the Westergren method with dilution only as prescribed by the "ICSH review of the measurement of the ESR" (2011) and the "CLSI Procedures for the ESR Test; Approved standard; H02-A5" (2011).

Citrate mode: When the StaRRsed analyzer is used in the Citrate mode, the StaRRsed Control material must be diluted manually by transferring the necessary amount of material into a pre-citrated ESR blood collection tube. Immediately after re-suspending, transfer the necessary amount of material into a pre-citrated tube according instructions of the tube manufacturer. Close the tube with the mixture and invert at least 12 times, then place the sample into the analyzer.

1. *When using LAB ID:* Link the Lab ID with StaRRsed Control Sample ID, see chapter ***Linked QC ID's*** (on page 40). Attach the lab ID label on the tube on top of the original StaRRsed Control label
2. Invert the StaRRsed Control tube until packed cells have been completely re-suspended. Continue mixing for 30 seconds (at least 12 complete inversions).
   Avoid foaming. DO NOT VORTEX.
   NOTE: To ensure consistent and reproducible results, the Control material must be thoroughly mixed and handled in the same manner each time.
3. Place StaRRsed Control tube immediately after mixing into the analyzer.
4. Start the Sample mode. The StaRRsed Control sample is processed in the same manner as a patient sample. Depending on the settings in "QC settings", a request and/or result is send to the LIMS.
5. Restore tube after each use (at 18°-30°C).

For detailed information see the StaRRsed Control Package Insert.

The contents of one tube of 5ml is sufficient for three Control samples. Do not mix residual material with material from other tubes. Do not re-use empty tubes.

The software interface is described in the chapter ***History screen*** (on page 24).

StaRRsed Control should be disposed of as medical waste.

8.2.6. QC Results

The measured QC results are compared with the Assay mean value and the acceptable range. The applicable values for the acceptable range depend on the user setting. See chapter "QC Settings" for more information.

If applicable, the QC result is reported to LIMS using the chosen settings regarding temperature correction, display of dilution rate and limit error settings.

8.2.6.1. QC Error messages

The general ESR errors and warnings are also applied on the QC results, see "***ESR Error and Warning code messages*** (on page 64)"

When the result is within range, no message is shown.

When the result is out of range an error message is shown in the status line of the Sample screen and the QC icon is blinking on the Sample screen. When the sample mode is started again by the operator, the following messages appears:
Last QC result was out of range! Continuing could produce incorrect results! Do you still want to continue?
Press "**Accept**" to continue sampling without performing a new QC, press "**Cancel**" to return and take appropriate action.

Messages when the general setting "Temperature Correction" is switched ON:

- "E116: QC is out of acceptable range!"
  The Sample mode is switched OFF automatically. Remaining filled pipettes are processed in the normal manner.

Messages when the general setting "Temperature Correction" is switched OFF:
The software always calculates a temperature corrected result because only temperature corrected results can be compared with the Assay mean value.

- "E116: QC is out of acceptable range!"
  The uncorrected and the corrected result are out of range.
- "E117: Uncorrected QC result is out of acceptable range, but corrected result is within range!"
  The uncorrected result is out of range, but the corrected result is within range.
- "E118: Uncorrected QC result is within acceptable range, but corrected result is out of range!"
  The uncorrected result is within range, but the corrected result is out of range.

See ***Quality control trouble shooting*** (on page 85) and ***QC Results screen*** (on page 32) for more details.

8.2.6.2. QC Result analysis

Authorized staff should identify and differentiate acceptable/unacceptable random errors and trends and/or shifts in systematic errors from the statistical data. Depending on the users Quality Control Procedures analytical results could be accepted or rejected.

Changes in QC results can be gradual or abrupt. Gradual changes can be caused by contamination and incidental environmental variations. Abrupt changes can be caused by change of QC material batch or possible hardware errors.

If results are continuously out of range due to significant difference between calculated mean and control value, but the statistics show precise results with small deviations, it should be considered to expand the acceptable assay range with QC Settings.

If results are incidentally out of range it is advised to perform a daily maintenance and/or fill and clean step and then perform another QC sample step before releasing patient results.

If results are not send to the LIMS QC Results can be exported to MS Excel CSV files for further analysis in lab's own Quality Control data system.

9. WASTE DISPOSAL

The waste container has a level sensor and as soon as the level sensor generates a waste error, the waste container must be emptied. The waste must be treated as potentially infectious (biohazardous) material and disposed of according to local regulations. Preferably, discard the complete waste container and replace it with a cleaned one. Press **[ESC]** to clear the error.

Disclaimer: Check your local environment rules about discharging the waste.

If the waste line is to be connected to a centralised waste collection system, the following requirements must be met:

1. Waste tube must not exceed 5 meters or 18 feet in length.
2. Drain height must not be higher than the original waste container inside the instrument.

Disclaimer: Check the specifications of the central waste system for rules about discharging the waste.

9.1. Replacing the waste container

1. Lift the left cover and pull the waste container forwards.
2. Unscrew the cap.
3. Place the new waste container and tighten the screw cap.
4. Lift the left cover and place the waste container back into the Compact.

Note: If you are re-cycling waste containers, make sure that they are bleached and rinsed thoroughly.

10. DATA SAFETY MANAGEMENT

The StaRRsed Auto-Compact has its own external PC. This means that all collected data is stored on the hard-disk of the external computer.

This means that all raw data and results are kept, irrespective of a power failure or if the instrument is un-intentionally turned off. After the start-up procedure the software checks whether there are any ESR's still outstanding. If so, these will be carried out first. After a power failure the sedimentation time (60 or 30 min.) may be exceeded. However, the start time is saved and therefore the actual sedimentation time can be checked.

Important system settings are kept in an internal Flash Eprom inside the instrument.
In case of corrupted files, the program will automatically load and use the backup files.

10.1. Power failure

If a power failure occurs it is recommended that the StaRRsed Auto-Compact is switched **OFF** by the power switch. When the power returns, the instrument can be switched **ON**. After the standard start-up process the StaRRsed Auto-Compact will continue to process the remaining samples.

11. TROUBLE SHOOTING

Occasionally small faults may cause major problems. This chapter may help to solve the most common faults and explain why a specific problem occurs.
A lot of the problems or errors are due to a lack of maintenance. Remember that this instrument operates with a considerable amount of whole blood, virtually undiluted, stores it in a pipette for one hour and then cleans pipettes for re-use. Therefore, it is important to keep to the maintenance schedules. It is recommended that trained service personnel checks and applies service to the instrument at least once a year. Errors which are not explained in this section can usually not be solved by the operator. Refer to the Service manual for more information (available only in English).

The error numbers are displayed in the PC software.

11.1. General error procedure

Whenever an error occurs, follow the instructions given in the error message on screen. If no instructions are given, follow this general procedure:

1. Clear the error by pressing button CLEAR ERROR.
2. When the error is not cleared or the error occurs again:
3. Close the StaRRsed Auto-Compact PC software.
4. Switch the Compact OFF.
5. Switch the Compact ON.
6. Start the StaRRsed Auto-Compact PC software.

When the error occurs again, switch OFF all units and call for service.

11.2. Flushing liquids

After each sample aspiration the entire system is washed automatically.
If there is no liquid flow:

- Check that the peristaltic pumps are running. If the pump tubes are worn or leaking, replace the tubes.
- Check that the pump tubes are installed correctly.
- Check the tubes between the containers and pumps/valves.
- Unscrew the cap from the container. Check the pick-up tubes in the container and that there is enough liquid in the container.
- Check the tubes for blockages or kinks.

11.3. Reagents

Check the expire dates of the reagents regularly. Do not use the reagents if expired.

Note: If expired reagent has been used accidentally, the results obtained with these reagents may only be used, when the expire date was not exceeded more than 30 days.

DILUENT is sensitive for bacterial growth. The solution should be discarded if it becomes turbid or infected. When using the small onboard containers, clean the DILUENT container thoroughly with 10% Na-hypochlorite. Make sure that the container has been thoroughly rinsed after cleaning.

11.3.1. Reagents alarm

The software checks the bottle status before starting a new rack. If a level alarm is **ON**, it will not process the new rack. If an alarm comes **ON** during a rack, it will finish to aspirate that rack (10 samples max.). Washing dirty pipettes always continues, as to avoid that the samples are left in the pipettes.

Reagents alarm is also set when the expire date of the reagent is exceeded or opened more than three months. The message Not allowed now! See REAGENTS! appears. Processing of new samples is stopped.

11.4. Separator error

If it takes too long for the waste pump to empty the liquid separator, the system generates a separator error.

Separator error may be caused by:	
Extensive foam build-up in the liquid separator.	Check the separator assembly and connections for possible air leaks.
Waste-tube between liquid separator and waste pump is blocked.	Replace the tube.
Waste-tube between waste pump and waste container blocked.	Replace the tube.
Waste pump failure.	Exchange the waste pump cassette. If the error returns, call for service.
Electrical bridge between the waste-level electrodes.	Clean liquid separator, see ***WI-196 Cleaning liquid separator*** (on page 112)

11.5. Fill time-out error

Normally the fill sequence takes about 3 seconds. However, if the fill sequence exceeds 10 seconds, a fill time-out error will be generated. The Compact aborts the fill sequence and this error message will be shown on the display and reported to the printer.

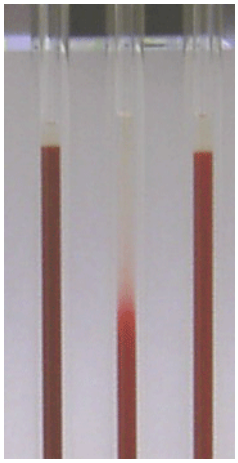
Fill time-out error may be caused by:

1. Blood clots or rubber debris from the tube cap in the sample.
   - Check the condition of the outer needle.
   - Check the mixing time of the tube SETTINGS - GENERAL SETTINGS - MIXING INTERVAL <default 90 sec>
2. Filling procedure stopped by operator.
3. Insufficient sample volume.
   - Should be at least 1.4 ml.
4. Faulty fill nozzle or fill nozzle washer/O-ring.
   - Check fill nozzle and washer/O-ring.
5. Incorrectly adjusted sample probe depth.
   - Check needle depth SETTINGS - GENERAL SETTINGS - SAMPLE PROBE DEPTH <default 5 mm>
6. No or poor vacuum.
   - Check vacuum MAINTENANCE - CHECK SENSORS - CHECK FLOW SENSOR

11.6. Hazy reports

"Hazy" reports are usually caused by build-up of proteins on the inner wall of the pipettes. Another cause is growth of micro organisms in the diluter system. It is extremely important that the system is kept sterile.

First run an extra Fill & Clean sequence, then check after a day's run if haziness is decreased. When there are still many reports, it is recommended to fill the diluter system with a 5% chlorine solution. See ***WI-178 Hazy problem*** (on page 109).



A picture example of haziness

11.7. Leaking pipettes

1. Check for particles like specks of dirt or hairs in the pipette valve.
2. If no particles are found, replace the valve tube and valve body.

11.8. Liquid level sensor not sensing

1. Liquid in the container is not detected. This occurs sometimes with the DE-IONIZED WATER bottle and is caused by a very low conductivity.
2. Add one or two drops of SALINE to the DE-IONIZED WATER to increase the conductivity.

11.9. Air bubbles

After a normal aspiration, the Westergren pipette must be free of air bubbles. In the following examples different patterns of air bubbles which can appear in the pipettes are shown. Air bubbles can affect the sedimentation and are mostly reported as errors and no ESR result is reported.

Usually bubbles are caused by a leakage at the bottom of the pipette. If air bubbles are visible in the pipette, check the following :

11.9.1. Pipette looks like zebra crossing

If this always occurs in the same pipette, check the bottom of the pipette for the following:

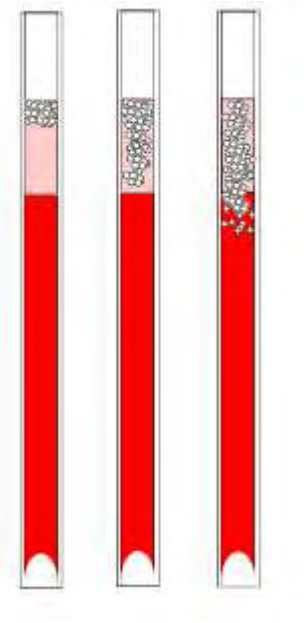
1. Glass may be chipped.
   - Replace pipette.
2. Dirt, e.g. dried blood.
   - Clean the pipette.
   - Check disinfectant flow at the rinse nozzle.
3. Perpendicularity and straightness of the bottom face.
   - Replace pipette.

If this happens randomly or with each pipette, check the following:

1. Fill nozzle O-ring or flat washer.
2. Fill nozzle alignment to pipette.
   - Check the nozzle arm is tight on the rear vertical shaft. Usually engineer's assistance is required.

A pipette which looks like zebra crossing gives ESR Error 3.

11.9.2. Foam in column



A layer of air bubbles that is concentrated on top of the blood column does not affect the sedimentation process itself. The sedimentation develops normally below the bubbles. However, too many bubbles bring about a shortening of the effective blood column, which is a deviation from the Westergren method.

A layer of bubbles up to 5 mm: No message. Normal ESR result is reported.

A layer of bubbles from 5 to 25 mm: ESR warning 6: "Bubbles on top". Results should be reviewed before release.

A layer of bubbles larger than 25 mm: ESR Error 3: "Too many borders found". No ESR result is given.

1. Check that tube connections are not leaking.
2. Check the fill nozzle condition:
   - Inspect for any cracks or deep scratches in the base that holds the fill nozzle washer or O-ring.
3. Check for air in diluter system.
4. Check that the sample probe O-ring is not leaking.
5. Check transparent T- piece or Y-piece block for cracks.

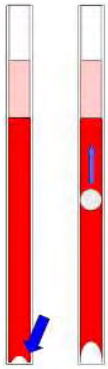
11.9.3. One air bubble about 5 mm under meniscus

The filling (aspiration) speed is not critical but should be within certain limits.

1. If just one air bubble is found about 5mm below the meniscus, the filling speed may be too high.
2. The blood column should not exceed the filling height sensor by more than 10mm.

One air bubble can result in ESR Error 3.

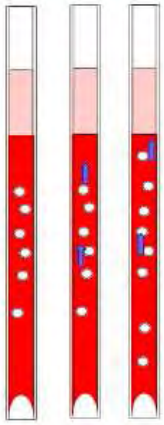
11.9.4. One air bubble rising in pipette



1. Usually this is caused by a wet or dirty fill nozzle.
   - The blood column should not reach right to the base of the pipette. There must be a clear air gap of 4...5mm at the bottom of each pipette.
2. Insufficient sample volume.
   - Need more blood in the sample tube.

One air bubble rising can result in ESR Error code 3.

11.9.5. Small air bubbles rising in pipette



Usually this is caused by a dirty or damaged fill nozzle.

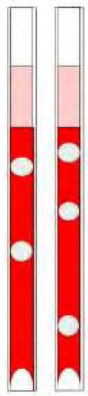
- Observe the maintenance schedules.
- Clean the fill nozzle.
- Check the fill nozzle for damage. If necessary, replace the fill nozzle.

Sample tube is leaking on the fill nozzle side.

- Replace the silicon sample tube

Small air bubbles result in ESR Error 3.

11.9.6. Random air bubbles in pipette



1. Check Diluent flow by priming the diluter system.
2. Insufficient sample volume.

Random air bubbles result in ESR Error 3.

11.10. Quality control trouble shooting

Error messages	Extra information	Action
E115: QC expired, not sampled!	The used StaRRsed Control is out of date, no ESR result is given	• Check expire date • Use a new batch of StaRRsed Control
E116: QC is out of acceptable range!	Result is out of range, the applicable values for the acceptable range depend on the user setting. E116 is shown in the status line of the Sample screen and the QC icon is blinking on the Sample screen. ESR Result is given.	• Try new QC sample tube (normal samples will be finished) • Check acceptable range in QC settings. If results are continuously out of range but the statistics show identical/stable results, it should be considered to expand the acceptable assay range with QC Settings • If this error persists check/clean instrument
E117: Uncorrected QC result is out of acceptable range, but corrected result is within range!	ESR Result is given. Temperature correction not activated.	• Consider QC Sample as correct. The mean value is assayed with temperature correction • Check temperature correction setting.
E118: Uncorrected QC result is within acceptable range, but corrected result is out of range!	ESR Result is given. Temperature correction not activated.	• Consider QC Sample as not correct • Try new QC sample tube (normal samples will be finished) • Check acceptable range in QC settings • If this error persists check/clean instrument • Check temperature correction setting.
QC result with ESR error	no ESR Result is given	• Check general ESR data, see ***ESR Error*** (on page 64) • Check sample tube volume • Try new QC sample tube

QC result with ESR warning	ESR Result is given	• Check general ESR data, general ***ESR Warnings*** (on page 64) • Check limit settings
Screen messages	**Extra information**	**Action**

QC icon is blinking at Sample screen	The last QC sample was not within acceptable range or has no result	• Press on QC icon
		  • Press "Accept" to continue sampling without performing a new QC, continuing could produce incorrect results.
		  • Press "Cancel" to return. Try new QC sample tube (normal samples will be finished)

QC result out of range!		• Perform a new QC sample, normal samples will be finished • If this error persists check/clean instrument
QC sample expired!		• Use a new batch of Starrsed Control
It is not possible to link this Lab ID. Lab ID is already linked!	The "Linked QC ID's" table may only contain one link to a particular Lab ID.	• Consider changing AUTOMATICALLY REMOVE LINKED QC ID AFTER RESULT option to YES
Last QC result was out of range! Continuing could produce incorrect results! Do you still want to continue?	Result of last QC sample was not within acceptable range.	• The last QC result should be evaluated by authorized staff to decide whether the StaRRsed Auto-Compact may run patient samples depending on the the nature of errors • Press "Yes" to continue sampling without performing a new QC, press "No" to return and take appropriate action.
General errors	**Extra information**	**Action**
Barcode is not accepted	Barcode cannot be read Data is incorrect	• Check barcode

QC sample is not accepted and not performed	StaRRsed Control ID is not known in LIMS.	• Check barcode
QC result is not visible in QC History	A specific QC result cannot be found in the list of results.	• Check Lab-ID link
Deviating results	**Extra information**	**Action**
Systematic QC errors with a shift in control values (QC results are out of range)	The measured control values change abruptly up- or downwards. Do not compare 30 minute method with 60 minute method result. The calculation method can give some deviation in the general QC results statistics.	• Check/clean instrument and perform a new QC sample • If these errors persist perform maintenance step • Compare only results from one batch. • If Lab ID is used check the linked StaRRsed Control ID. It is possible that a new batch is in use without changing to the new assayed mean value
Systematic QC errors with a trend in control values (QC results out of the range or nearly out of the range)	The measured control values change gradually upwards or downwards.	• Irregular or insufficient maintenance can cause unnecessary QC errors and ESR errors/warnings

Note on QC Errors

Error messages are only shown and stored in QC results and not send to LIMS.

QC result is given with the same general errors and warnings as a normal patient ESR-result

12. MAINTENANCE

The **StaRRsed Auto-Compact** is an analyzer that operates with considerable amounts of whole blood virtually undiluted, and stores it in a pipette for one hour. For this reason instrument maintenance is of the utmost importance.

To maintain the maximum reliability of the instrument, the maintenance procedures must be strictly followed. All procedures are based on a number of samples.

Maintenance levels	(WI) Work instruction
Daily	***WI-187 Daily maintenance*** (on page 98)
Weekly	***WI-191 Weekly maintenance*** (on page 99)
Level 4 Maintenance	***WI-193 level 4 maintenance*** (on page ***102***) Every 3500 samples
Level 3 Maintenance	WI-194 Level 3 maintenance Every 10000 samples

WARNING!!!
Always be aware of the danger of infection, especially during maintenance. Take appropriate precautions. There is blood involved and therefore a **BIO HAZARD**

12.1. Daily

The purpose of the daily maintenance is to keep the instrument clean and contamination as low as possible.
Clean all parts that are exposed to blood, wipe the outer surface and the stainless steel plate below the pipette belt. See ***WI Daily maintenance*** (on page 98).

12.1.1. Check or replace sample probe or outer needle

A faulty or broken needle can cause a fill time-out error or a dilution error.
Inspect sample needle condition each day, clean if necessary.
If necessary replace the sample probe or outer needle.

Remove the top cover from the Rack unit.

1. Unfasten the screw which prevent the outer needle to drop out of the assembly.
2. Undo the sample probe.
3. Pull the outer needle complete with sample probe together out the needle assembly.
4. Mark each tube for easier reconnecting to the correct nipple.
5. Disconnect the tubes from the outer needle.

Needle exchange:

1. Install (new) sample probe ESRI050909 together with a new outer needle VERA059009
2. Slide the new sample probe into the (new) outer needle.
3. Make sure the Sample probe has a (new) O-ring QWLV050003.
4. Install (new) sample probe ESRI050909 together with the (new) outer needle
5. Put the sample probe in the outer needle.
6. Replace the needles onto the needle assembly.

7. Tighten the sample probe. Do not over-tighten the sample probe in the T-piece / Y-piece or it will crack or strip the threading inside the block.
8. Replace the correct tubes on the outer needle.
9. Fasten the outer needle bolt.(Do not over-tighten the screw)
10. Replace the cover on the Rack unit.

12.2. Weekly

The purpose of the weekly maintenance is to carry out the daily maintenance and additionally check the optical sensor of the measure head and the vacuum pressure.
Detailed instructions of this procedure can be found in the Work Instruction ***Weekly maintenance.*** (on page 99)

12.2.1. Check the sensors in service mode

Vacuum pressure check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK FLOW SENSOR box.
  Flow: 0925-**0980**-1020 Abs: 0300-**360**-0390 Offset: 0045-**0050**-0055
  If the flow is not in range there might be a blockage in the vacuum flow line to the flow sensor.

Fill Stop sensor check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK FILL STOP SENSOR box.
  Fill stop sensor FS 90..**140**..165

Diluter Start sensor check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select DILUTER START SENSOR box.
  Diluter start sensor 400-700

Measure sensor check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK MEASURE SENSOR box.
  Measure sensor MS 40..**50**..60

Temperature sensor check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK TEMPERATURE SENSOR box.
  Temperature sensor TS [Room temperature]

Diluent flow sensor check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK DILUENT FLOW SENSOR box.
  Press test. When test is finished, signal Down and signal Up must be green.

Separator check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK SEPARATOR SENSOR box.
  Separator sensor <200 600 >700

12.2.2. Cleaning liquid separator

The separator is designed to separate liquid from the air and can handle a lot of blood, rinse and other used reagents from the instrument. After a period of time the separator is getting dirty and therefore it needs to be cleaned weekly.

Detailed instructions of this procedure can be found in the Work Instruction **WI-196 Cleaning liquid separator (on page 112).**

Symptoms of a dirty separator:

1. Separator errors.
2. Foam in the separator.
3. Waste pump cannot sufficiently remove the waste from of the separator.

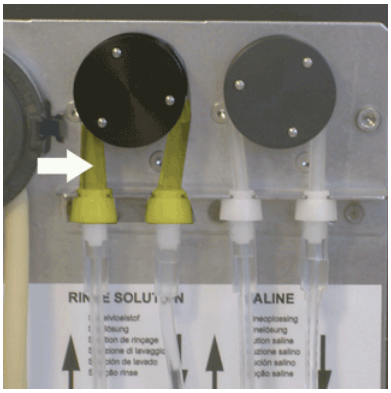
12.3. Level 4 maintenance

The purpose of level 4 maintenance is to carry out the daily / weekly maintenance and replace the pump tubing, bacterial filters and the Fill nozzle O-ring. After replacing those items, the instrument needs a Fill and Clean sequence to clean the pipettes. Over a monthly period protein builds up in the Westergren pipettes and needs to be deproteinized using a strong cleaning agent.

Detailed instructions of this procedure can be found in the Work Instruction ***WI-193 level 4 maintenance*** (on page 102).

12.3.1. Rinse-pump tube replacement

New rinse pump tube assembly **ESRI090902**.



New tube replacement:

1. Open left cover.
2. Pull pump tube slightly downwards and at the same time towards the front of the unit to release the tube out of the pump plate holder.
3. Remove the old tube from the peristaltic pump rotor.
4. Disconnect the tubing at both ends of the tube connectors.
5. Connect new tubing to both ends of the connectors.
6. Place one end of the tube in the pump plate holder.
7. Pull the new tube over the peristaltic pump rotor.

8. Pull pump tube slightly downwards and at the same time towards the back of the StaRRsed Auto-Compact.

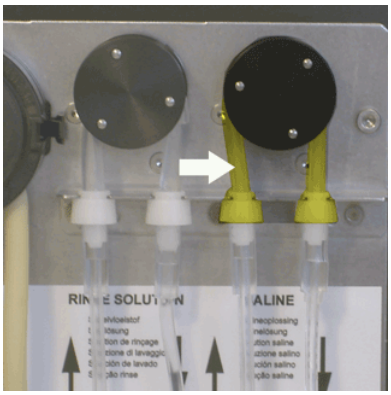
If the tube is not fitted correctly or is worn the following symptoms can occur.

- Liquid flowing back into the container.
- First glass tube on the pipette belt is not washed sufficiently.

Note: The wider bore tube is for the rinse pump.

12.3.2. Saline-pump tube replacement

New saline pump tube assembly **ESRI090903**



New tube replacement:

1. Open left cover.
2. Pull pump tube slightly downwards and at the same time towards the front of the unit to release the tube out of the pump plate holder.
3. Remove the old tube from the peristaltic pump rotor.
4. Disconnect the tubing at both ends of the tube connectors.
5. Connect new tubing to both ends of the connectors.
6. Place one end of the tube in the pump plate holder.
7. Pull the new tube over the peristaltic pump rotor.
8. Pull pump tube slightly downwards and at the same time towards the back of the StaRRsed Auto-Compact.

If the tube is not fitted correctly or is worn the following symptoms can occur.

- Liquid flowing back into the container.
- Sample needle is not washed sufficiently.

Note: The narrower bore tube is for the saline pump.

12.3.3. Replace bacterial filters

Detailed instructions of this procedure can be found in **WI-196 Cleaning liquid separator (on page 112).**

As part of the Cleaning liquid separator procedure the bacterial Hepa filter **QWLV040002** is replaced with a new one.

Exchange bacterial filter **QWLV040001** on the waste bottle assembly.

12.3.4. Fill-nozzle O-ring replacement

As the fill nozzle O-ring (**QWLV050004**) ages, it looses its flexibility and air-bubbles may occur in the Westergren pipettes, the washer needs to be replaced.

Symptoms for a bad fill-nozzle O-ring
After the aspiration, the Westergren pipette has a zebra pattern (air- blood- air -blood, nicely divided in the column.)
Vacuum stabilisation errors may occur.

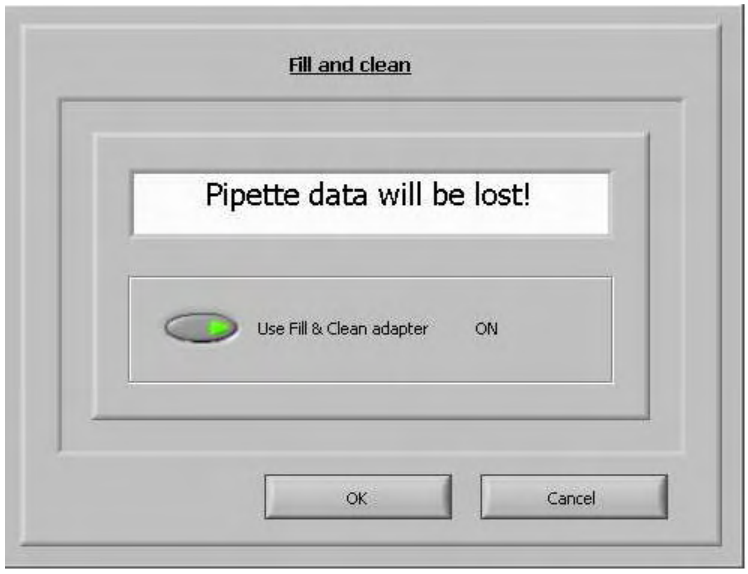
12.3.5. Fill and clean procedure

Note: Each pipette on the pipette belt will be filled with cleaning agent, after one hour the first pipette is washed and dried. Fill and clean takes about 1 ½ hours to complete.

Fill and clean with adapter:

Cleaning agent preparation Auto Compact: Fill and clean:
This cycle takes about 90 minutes.

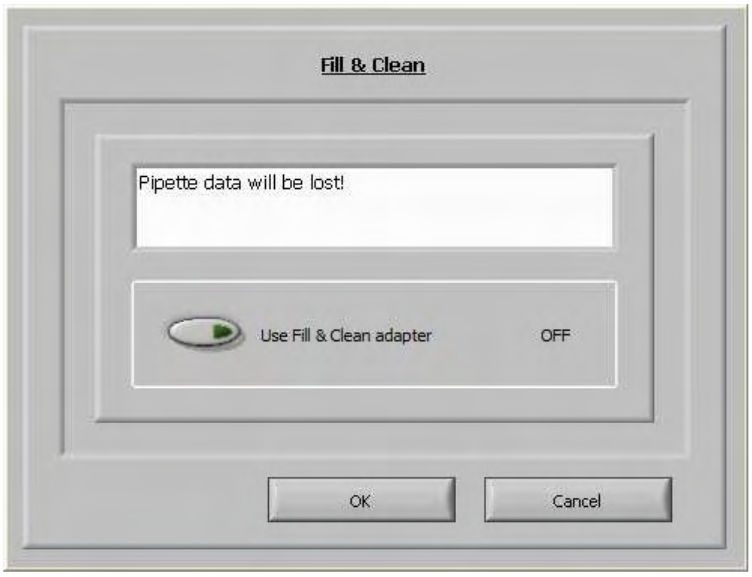
1. Fill the clean adapter VERA119002 with hot de-ionized water till the first mark in the adapter. (180 ml).
2. Add cleaning agent (QRR 010905) till the second marker in the adapter. (18 ml).
3. Place the two caps on the adapter and mix well.
4. Put the adapter in the Input-pool.
5. Select MAINTENANCE - PRIME/CLEAN, button FILL AND CLEAN.

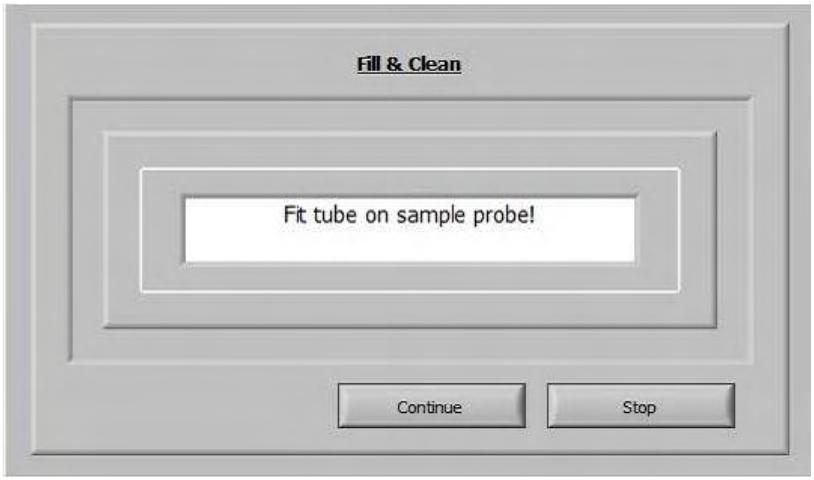


Start Fill and clean procedure:

1. Select button **OK**.
2. The adapter will be transported to the needle position.
3. The needle goes down and the fill and clean process is started.
4. When all the pipettes are filled, the needle goes back to the home position and the adapter is moved to the release position and will be transported into the End-pool.

Fill and clean without adapter:





1. The gripper moves to the needle position.
2. The needle comes down.
3. Fill a container with 150 ml hot de-ionized water.
4. Add 15 ml cleaning agent. (QRR 010905)
5. Stir the prepared solution.
6. Put the container close to the needle location.
7. Push the silicon tube over the sample probe.
8. Press CONTINUE.
9. The fill and clean process is started.

See also ***WI-178 Hazy problems*** (on page 109) and WI-195 Cleaning the diluent system (Cleaning with Chlorine).

12.4. Reagents replacement

The StaRRsed Auto-Compact can be used with the small onboard reagent containers or with the genuine Mechatronics bulk reagent containers if long level sensors are available.

After each reagents change, the fluid system must be primed:

1. Select MAINTENANCE -> PRIME / CLEAN (on page 51).
2. Perform the applicable prime step to fill the relevant tubes with reagent and remove air.

For AutoCompact LS:

To replace the bulk reagent containers:

1. Remove level sensors and spacers from the empty container.
2. Remove empty container.
3. Place new container.
4. Remove the container screw caps and pull the necks of the bottle packs out of the cardboard box.

5. Install the level sensors and spacers according the following pictures.
   Make sure to place the appropriate level sensors in the containers by matching the color codes on the tube and on the container:

The sensors and the reagents have the following numbers and color codes:

Reagent	Connector number	Color code
RINSE SOLUTION	Number 34	Green
SALINE	Number 35	Yellow
DILUENT	Number 36	Grey
DE-IONIZED WATER	Number 37	Blue
DISINFECTANT	Number 38	White

NOTE: Wrongly placed pickup tubes may cause incorrect results or instrument malfunction.

After each reagents change, the fluid system must be primed:

1. Select MAINTENANCE -> PRIME / CLEAN (on page 51).
2. Perform the applicable prime step to fill the relevant tubes with reagent and remove air.

13. WORK INSTRUCTION STARRSED AUTO-COMPACT

Work instruction section

Work instruction Number 187	
Page 1 of 1	**Purpose:** Daily maintenance
Safety: *Bio Hazard area*	
Instrument: Compact	**Revision:** 001, March 2014

Prepare disinfectant: (if not already prepared).
Add **10 ml** bleach (sodium hypochlorite) to **190 ml** de-ionized water. **(5% solution)**
This disinfectant is for cleaning of all external parts that are exposed to blood.

1. Go to tab [MAINTENANCE] and perform the [End-of-day wash] procedure. (when Fill & Clean is used, End-of-day wash is not required)
2. Check system for leakage.
   - Inspect the peristaltic pump tubes and connections for leaks.
   - Check that liquid does not run back into the supply bottles after the pumps have stopped.
3. Clean and inspect the sample needle.
   - Inspect sample needle condition.
     If necessary replace the sample probe or outer needle. See Work Instruction Sample probe or outer needle replacement.
   - Clean the outer needle with disinfectant.
4. Check tubing from the syringe for trapped air bubbles.
5. Check Diluent syringe for trapped air bubbles.
6. If trapped air bubbles are found, go to tab [MAINTENANCE], click button [PRIME / CLEAN (ON PAGE 51)] and perform the [PRIME DILUENT] function.
7. Wipe outer surface and stainless steel plate below the pipettes with disinfectant.

Work instruction Number 191	
Page 1 of 3	**Purpose:**Weekly maintenance
Safety: *Bio Hazard area*	
Instrument: Compact	**Revision:** 001, March 2014

Prepare disinfectant: (if not already prepared).
Add **10 ml** bleach (sodium hypochlorite) to **190 ml** de-ionized water. **(5% solution)**
This disinfectant is for cleaning of all external parts that are exposed to blood.

1. Clean Fill nozzle

Disassemble the fill-nozzle:

1. Turn the holder to the right.
2. The fill-nozzle can now be removed.
3. Disconnect the silicon tube from the fill nozzle.

The use of a toothbrush and detergent is recommended.

1. Carefully scrub the fill nozzle inner part.
2. Use a tissue to dry the fill nozzle.

Assemble fill-nozzle:

1. Connect the silicon tube to the fill nozzle.
2. Put the fill nozzle into the holder.
3. Push the fill nozzle upwards and turn the holder to the left.

2. Clean Liquid separator

Removing

1. Open the left cover and remove the waste container. The liquid separator is now visible.
2. Lift the stainless steel vacuum tube with use of the lever.
3. Pull the liquid separator towards the front of the Compact. (Note: The separator has two sensor connectors at the rear)
4. Disconnect the silicon tube from the tube connection on the top section.
5. Remove bacterial HEPA filter.
6. Remove and disassemble the liquid separator.

Cleaning

1. Clean all parts with hot water and a brush.
2. Use some acid free vaseline on the screw-thread of the glass jar.
3. Assemble the separator.

Replacing

1. Replace the top section.
   A little silicon grease on the rim of separator will make the assembling and adjustment easier.
2. If applicable replace the bacterial HEPA filter
   (For Maintenance Level 4: Exchange bacterial HEPA filter QWLV040002)
3. Re-connect the silicon tube to the tube connector on the top section.
4. Lift left cover.
5. Lift stainless steel vacuum tube up.
6. Insert the liquid separator sliding it over the support shelf.
7. Push the liquid separator towards the rear, with the sensor connectors in the holes.
8. Release the stainless steel vacuum tube.
9. Replace the waste container.
10. Close left cover.

3. Check sensors

Vacuum pressure check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK FLOW SENSOR box.
  Flow: 0925-**0980**-1020 Abs: 0300-**360**-0390 Offset: 0045-**0050**-0055
  If the flow is not in range there might be a blockage in the vacuum flow line to the flow sensor.

Fill Stop sensor check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK FILL STOP SENSOR box.
  Fill stop sensor FS 90..**140**..165

Diluter Start sensor check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select DILUTER START SENSOR box.
  Diluter start sensor 400-700

Measure sensor check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK MEASURE SENSOR box.
  Measure sensor MS 40..**50**..60

Temperature sensor check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK TEMPERATURE SENSOR box.
  Temperature sensor TS [Room temperature]

Diluent flow sensor check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK DILUENT FLOW SENSOR box.
  Press test. When test is finished, signal Down and signal Up must be green.

Separator check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK SEPARATOR SENSOR box.
  Separator sensor <200 600 >700

4. Final preparation

1. Go to tab [MAINTENANCE] and perform the [End-of-day wash] procedure. (when Fill & Clean is used, End-of-day wash is not required)
2. Check system for leakage.
   - Inspect the peristaltic pump tubes and connections for leaks.
   - Check that liquid does not run back into the supply bottles after the pumps have stopped.
3. Clean and inspect the sample needle.
   - Inspect sample needle condition.
     If necessary replace the sample probe or outer needle. See Work Instruction Sample probe or outer needle replacement.
   - Clean the outer needle with disinfectant.
4. Check tubing from the syringe for trapped air bubbles.
5. Check Diluent syringe for trapped air bubbles.
6. If trapped air bubbles are found, go to tab [MAINTENANCE], click button [PRIME / CLEAN (ON PAGE 51)] and perform the [PRIME DILUENT] function.
7. Wipe outer surface and stainless steel plate below the pipettes with disinfectant.

Work instruction Number 193	
Page 1 of 5	**Purpose:** Maintenance level 4
Safety: *Bio Hazard area*	
Instrument: Auto Compact	**Revision:** 002, March 2014

1. Clean Fill nozzle and exchange O-ring Fill Nozzle

Disassemble the fill-nozzle:

1. Turn the holder to the right.
2. The fill-nozzle can now be removed.
3. Disconnect the silicon tube from the fill nozzle.

The use of a toothbrush and detergent is recommended.

1. Carefully scrub the fill nozzle inner part.
2. Use a tissue to dry the fill nozzle.

Disassemble fill nozzle holder:

1. Turn the holder to the right.
2. The holder can now be removed

Replace O-ring:

Remove the O-ring. (**QWLV050004**)

Install new O-ring. (**QWLV050004**)

Assemble fill nozzle holder:

Push the plastic top part down against the spring pressure.

1. Turn the plastic top part until you hear of feel a click
2. Turn the plastic top part clokwise for 1.5 turns.

Assemble fill-nozzle:

1. Connect the silicon tube to the fill nozzle.
2. Put the fill nozzle into the holder.
3. Push the fill nozzle upwards and turn the holder to the left.

2. Clean Liquid Separator and exchange filters

Removing

1. Open the left cover and remove the waste container. The liquid separator is now visible.
2. Lift the stainless steel vacuum tube with use of the lever.
3. Pull the liquid separator towards the front of the Compact. (Note: The separator has two sensor connectors at the rear)
4. Disconnect the silicon tube from the tube connection on the top section.
5. Remove bacterial HEPA filter.
6. Remove and disassemble the liquid separator.

Cleaning

1. Clean all parts with hot water and a brush.
2. Use some acid free vaseline on the screw-thread of the glass jar.
3. Assemble the separator.

Replacing

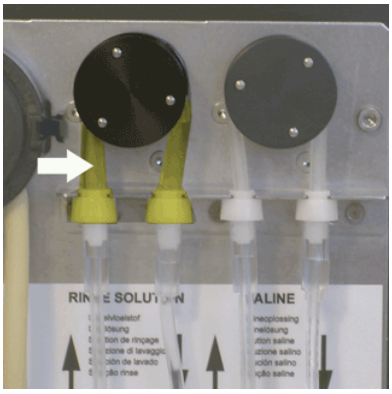
1. Replace the top section.
   A little silicon grease on the rim of separator will make the assembling and adjustment easier.
2. If applicable replace the bacterial HEPA filter
   (For Maintenance Level 4: Exchange bacterial HEPA filter QWLV040002)
3. Re-connect the silicon tube to the tube connector on the top section.
4. Lift left cover.
5. Lift stainless steel vacuum tube up.
6. Insert the liquid separator sliding it over the support shelf.
7. Push the liquid separator towards the rear, with the sensor connectors in the holes.
8. Release the stainless steel vacuum tube.
9. Replace the waste container.
10. Close left cover.

On waste bottle (If used):

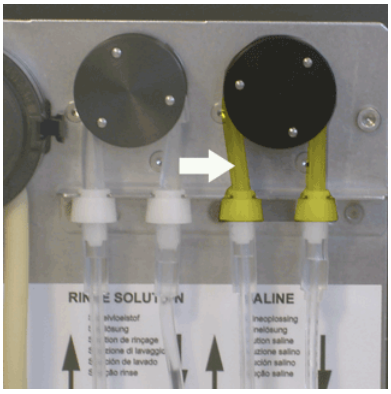
Exchange bacterial filter **QWLV040001** on the waste bottle assembly.

3. Exchange Rinse and Saline tube assembly

New rinse pump tube assembly **ESRI090902**.



New saline pump tube assembly **ESRI090903**



New tube replacement:

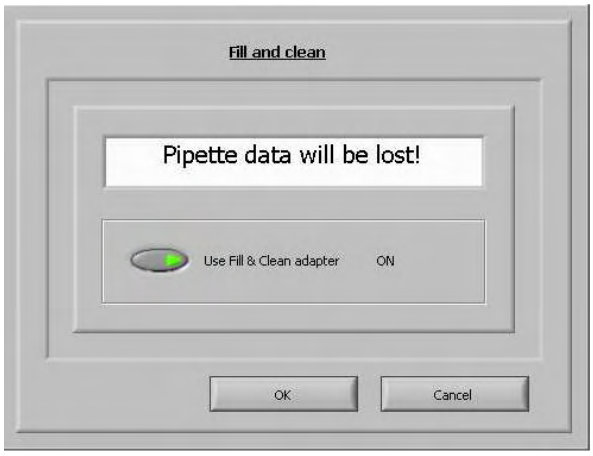
1. Open left cover.
2. Pull pump tube slightly downwards and at the same time towards the front of the unit to release the tube out of the pump plate holder.
3. Remove the old tube from the peristaltic pump rotor.
4. Disconnect the tubing at both ends of the tube connectors.

5. Connect new tubing to both ends of the connectors.
6. Place one end of the tube in the pump plate holder.
7. Pull the new tube over the peristaltic pump rotor.
8. Pull pump tube slightly downwards and at the same time towards the back of the StaRRsed Auto-Compact.

4. Fill and clean

Cleaning agent preparation Auto Compact: Fill and clean:
This cycle takes about 90 minutes.

1. Fill the clean adapter VERA119002 with hot de-ionized water till the first mark in the adapter. (180 ml).
2. Add cleaning agent (QRR 010905) till the second marker in the adapter. (18 ml).
3. Place the two caps on the adapter and mix well.
4. Put the adapter in the Input-pool.
5. Select MAINTENANCE - PRIME/CLEAN, button FILL AND CLEAN.



Start Fill and clean procedure:

1. Select button **OK**.
2. The adapter will be transported to the needle position.
3. The needle goes down and the fill and clean process is started.
4. When all the pipettes are filled, the needle goes back to the home position and the adapter is moved to the release position and will be transported into the End-pool.

5. Sensor check

Vacuum pressure check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK FLOW SENSOR box.
  Flow: 0925-**0980**-1020 Abs: 0300-**360**-0390 Offset: 0045-**0050**-0055
  If the flow is not in range there might be a blockage in the vacuum flow line to the flow sensor.

Fill Stop sensor check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK FILL STOP SENSOR box.
  Fill stop sensor FS 90..**140**..165

Diluter Start sensor check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select DILUTER START SENSOR box.
  Diluter start sensor 400-700

Measure sensor check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK MEASURE SENSOR box.
  Measure sensor MS 40..**50**..60

Temperature sensor check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK TEMPERATURE SENSOR box.
  Temperature sensor TS [Room temperature]

Diluent flow sensor check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK DILUENT FLOW SENSOR box.
  Press test. When test is finished, signal Down and signal Up must be green.

Separator check

- Go to tab MAINTENANCE -> CHECK SENSOR. Select CHECK SEPARATOR SENSOR box.
  Separator sensor <200 600 >700

6. Final preparation

Prepare disinfectant: (if not already prepared).
Add **10 ml** bleach (sodium hypochlorite) to **190 ml** de-ionized water. **(5% solution)**
This disinfectant is for cleaning of all external parts that are exposed to blood.

1. Go to tab [MAINTENANCE] and perform the [End-of-day wash] procedure. (when Fill & Clean is used, End-of-day wash is not required)
2. Check system for leakage.
   - Inspect the peristaltic pump tubes and connections for leaks.
   - Check that liquid does not run back into the supply bottles after the pumps have stopped.
3. Clean and inspect the sample needle.
   - Inspect sample needle condition.
     If necessary replace the sample probe or outer needle. See Work Instruction Sample probe or outer needle replacement.

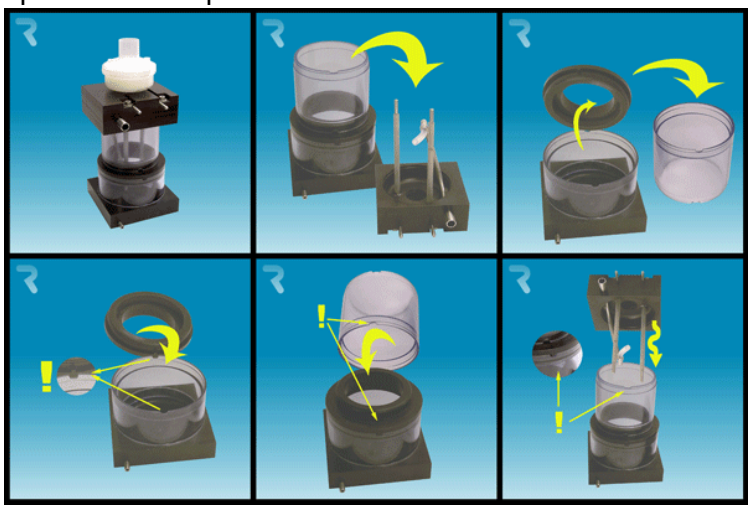
- Clean the outer needle with disinfectant.

4. Check tubing from the syringe for trapped air bubbles.
5. Check Diluent syringe for trapped air bubbles.
6. If trapped air bubbles are found, go to tab [MAINTENANCE], click button [PRIME / CLEAN (ON PAGE 51)] and perform the [PRIME DILUENT] function.
7. Wipe outer surface and stainless steel plate below the pipettes with disinfectant.

Work instruction Number 169	
Page 1 of 3	**Purpose:**Cleaning liquid separator
Safety: *Bio Hazard area*	
Instrument: Compact:	**Revision:** Draft, October 2001

Prepare disinfectant: (if not already prepared).
Add **10 ml** bleach (sodium hypochlorite) to **190 ml** de-ionized water. **(5% solution)**
This disinfectant is for cleaning of all external parts that are exposed to blood.
Clean liquid separator

1. Open the left cover and remove the waste container. The liquid separator is now visible.
2. Lift the stainless steel vacuum tube with use of the lever.
3. Pull the liquid separator towards the front of the Compact. (Note: The separator has two sensor connectors at the rear)
4. Disconnect the silicon tube from the tube connection.
5. Remove bacterial HEPA filter.
6. Open the liquid separator by pulling off the top section.
7. Clean the internal parts of the separator with disinfectant.



Replacing

1. Replace the top section.
   A little silicon grease on the rim of separator will make the assembling and adjustment easier
2. If applicable replace the bacterial HEPA filter
   (For Maintenance Level 4 exhange bacterial HEPA filter QWLV040002)
3. Re-connect the silicon tube to the bottom tube connector.
4. Lift left cover.
5. Lift stainless steel vacuum tube up.
6. Insert the liquid separator sliding it over the support shelf.
7. Push the liquid separator towards the rear, with the sensor connectors in the holes.
8. Release the stainless steel vacuum tube.
9. Replace the waste container.
10. Close left cover.

Work instruction Number 178	
Page 1 of 1	**Purpose:** Hazy problems
Safety: *Bio Hazard area*	
Instrument: StaRRsed Auto-Compact	**Revision:** 002, December 2013

Prepare disinfectant:
Add **10 ml** bleach (sodium hypochlorite) to **190 ml** de-ionized water. **(5% solution)**

Cleaning the diluent system:

Step 1

1. Remove the suction-tube from the diluent bottle.
2. Place the suction tube in chlorine solution.
3. Use the [PRIME DILUENT] function. This fills the dispenser system with the disinfectant.
4. After the prime sequence stops press [PRIME DILUENT] 5 times to fill the dispenser system with the disinfectant.
5. Leave the disinfectant in the system for 15 minutes.

Step 2

1. Take the diluent suction tube out of the disinfectant.
2. Wipe the tube clean and dry with a tissue.
3. Place the diluent suction tube in hot de-ionized water (80℃).
4. Use the [PRIME DILUENT] function.
5. After the prime sequence stops press [PRIME DILUENT] 5 times to fill the dispenser system with the hot water.

Step 3

1. Clean the diluent bottle(s) with the disinfectant.
2. Rinse the diluent bottle with hot de-ionized water (80℃).
3. Rinse the diluent bottle with diluent solution.
4. Refill the diluent bottle with new diluent solution.
5. Use the [PRIME DILUENT] function.
6. After the prime sequence stops press the [PRIME DILUENT] key 5 times to fill the dispenser system with the new diluent solution.

Step 4

1. Prepare a Fill and Clean arrangement.
2. Run the fill and clean sequence. When all the pipettes are filled the needle goes back to the home position.
3. Remove the Fill and clean arrangement.

Work instruction Number 189	
Page 1 of 1	**Purpose:** Sample probe or outer needle replacement
Safety: *Bio Hazard area*	
Instrument: Auto Compact	**Revision:** 001, October 2012

Remove the top cover from the Rack unit.

1. Unfasten the screw which prevent the outer needle to drop out of the assembly.
2. Undo the sample probe.
3. Pull the outer needle complete with sample probe together out the needle assembly.
4. Mark each tube for easier reconnecting to the correct nipple.
5. Disconnect the tubes from the outer needle.

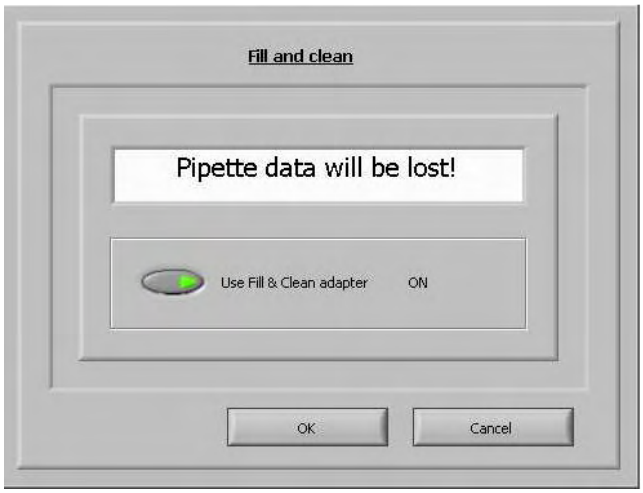
Needle exchange:

1. Install (new) sample probe ESRI050909 together with a new outer needle VERA059009
2. Slide the new sample probe into the (new) outer needle.
3. Make sure the Sample probe has a (new) O-ring QWLV050003.
4. Install (new) sample probe ESRI050909 together with the (new) outer needle
5. Put the sample probe in the outer needle.
6. Replace the needles onto the needle assembly.
7. Tighten the sample probe. Do not over-tighten the sample probe in the T-piece / Y-piece or it will crack or strip the threading inside the block.
8. Replace the correct tubes on the outer needle.
9. Fasten the outer needle bolt.(Do not over-tighten the screw)
10. Replace the cover on the Rack unit.

Work instruction Number 192	
Page 1 of 2	**Purpose:**Fill and Clean with adapter
Safety: *Bio Hazard area*	
Instrument: Auto Compact	**Revision:** 001, September 2012

Cleaning agent preparation Auto Compact: Fill and clean:
This cycle takes about 90 minutes.

1. Fill the clean adapter VERA119002 with hot de-ionized water till the first mark in the adapter. (180 ml).
2. Add cleaning agent (QRR 010905) till the second marker in the adapter. (18 ml).
3. Place the two caps on the adapter and mix well.
4. Put the adapter in the Input-pool.
5. Select MAINTENANCE - PRIME/CLEAN, button FILL AND CLEAN.



Start Fill and clean procedure:

1. Select button **OK**.
2. The adapter will be transported to the needle position.
3. The needle goes down and the fill and clean process is started.
4. When all the pipettes are filled, the needle goes back to the home position and the adapter is moved to the release position and will be transported into the End-pool.

Work instruction Number 196	
Page 1 of 1	**Purpose:** Cleaning liquid separator (Version 2)
Safety: *Bio Hazard area*	
Instrument: Compact	**Revision:** 002, March 2013

Removing

1. Open the left cover and remove the waste container. The liquid separator is now visible.
2. Lift the stainless steel vacuum tube with use of the lever.
3. Pull the liquid separator towards the front of the Compact. (Note: The separator has two sensor connectors at the rear)
4. Disconnect the silicon tube from the tube connection on the top section.
5. Remove bacterial HEPA filter.
6. Remove and disassemble the liquid separator.

Cleaning

1. Clean all parts with hot water and a brush.
2. Use some acid free vaseline on the screw-thread of the glass jar.
3. Assemble the separator.

Replacing

1. Replace the top section.
   A little silicon grease on the rim of separator will make the assembling and adjustment easier.
2. If applicable replace the bacterial HEPA filter
   (For Maintenance Level 4: Exchange bacterial HEPA filter QWLV040002)
3. Re-connect the silicon tube to the tube connector on the top section.
4. Lift left cover.
5. Lift stainless steel vacuum tube up.
6. Insert the liquid separator sliding it over the support shelf.
7. Push the liquid separator towards the rear, with the sensor connectors in the holes.
8. Release the stainless steel vacuum tube.
9. Replace the waste container.
10. Close left cover.

14. APPENDIX FOR STARRSED AUTO-COMPACT

Appendix section

Appendix - Error list Auto Compact

Last updated: 01-09-2014

Error	Extra explanation	Reason/Solution
E2: Communication error! (Board: %s (%x), Command: %x, TWSR: %x E: %d)	Communication lost after 3 retries between Computer and StaRRsed Auto-Compact.	• Power cable not connected on the communication PCB mounted on the back panel. • An I2C cable not connected • Serial cable not connected • No power on one of the PCB's • Short circuit or fault on one of the PCB's
E3: Measure motor timeout!	Measure head motor did not move or motor is blocked.	• Measure head is not at the Home position. • Check the Home sensor. • Motor is faulty. • Motor driver on drive board is faulty.
E4: Sample probe not in top position! (home)	Sample probe not back at Home position after sampling a tube.	• Check sample probe home sensor. • Sample probe motor is faulty. • Sample probe motor driver on needle board is faulty. • Sample probe is blocked.
E5: Duplicated ID !!	Sample rejected. Sample already in carousel.	• Wait until sample is measured • Check general settings (Check for duplicate ID's
E6: Program was not properly shut down. Check settings before continuing!	There is a possibility that changed settings which were not saved to disk are lost.	• Program stopped and computer needed to be reset. • Computer reset after power failure.

E7: Outer needle motor position error! Timeout! (piercing)	Outer needle did not go down within a certain time limit.	• Outer needle motor is faulty. • Outer needle motor driver on needle board is faulty. • Outer needle is blocked.
E8: Fillnozzle not in fill position!	Fill nozzle did not reach the fill position within a certain time limit.	• Fill nozzle motor is faulty. • Fill nozzle motor driver on nozzle board is faulty. • Fill nozzle is blocked.
E9: Air flow failure!	Compact was not able to get a stable reading during the vacuum test before aspiration the sample.	• Check for leakage on the pipette or fill nozzle.
E10: Sample probe was jammed. Check both needles before sampling!	Sample probe was probably jammed when going down and exceeded the maximum current level. Sample probe went back to its home position after the error.	• Check if outer needle is clogged up with rubber. • Sample probe maybe bend.
E11: Sample probe not on position (going down)! Timeout error!	Sample probe did not go down within a certain time limit.	• Sample probe motor is faulty. • Sample probe motor driver on needle board is faulty. • Sample probe is blocked.
E12: Dilution error: wrong or no diluent flow. Check the diluter!	Diluter malfunction	• Check diluent flow sensor • Check tubes diluter system
E13: Fillnozzle not in home position!	Fill nozzle did not reach the Home position within a certain time limit.	• Fill nozzle motor is faulty. • Fill nozzle motor driver on nozzle board is faulty. • Fill nozzle is blocked.
E14: Outer needle motor position error! (home)	Outer needle did not reach the home (top) sensor within a certain time limit.	• Check home (top) sensor. • Outer needle motor is faulty. • Outer needle motor driver on needle board is faulty. • Outer needle is blocked.

E18: Carousel position error! Check Rinse position.	Value of potentiometer does not match the value stored in memory of the current rinse position.	• Check if the rinse position is right. • Set correct rinse position and do a "Learn carousel positions". • Check mechanical connection potentiometers.
E19: Drive motor timeout!	Drive motor did not move or motor is blocked	• Check the home sensor • Motor is faulty • Motor driver on drive board is faulty
E20: Outer needle motor position error! (piercing error)	Outer needle could not go down all the way. Piercing position sensor was triggered.	• Check tube 1 position setting. • Tube 1 not aligned well. • Check piercing position sensor.
E21: No USB IO device detected. "Check USB IO Device" settings!	USB IO Device enabled but not detected.	• Check power to USB IO Device • Check USB cable • USB IO Device driver not installed • Check USB IO Device settings
E22: Waste bottle full!	Empty waste bottle and clear error.	• Check level sensor.
E23: "Fill " sensor out of range. Check/clean this sensor !	The Fill sensor has reached a critical level. Continuing could result in filling errors.	• Check and/or clean the Fill sensor.
E24: "Diluter Start" sensor out of range. Check/clean this sensor !	The Diluter Start sensor has reached a critical level. Continuing could result in filling errors.	• Check and/or clean the Diluter Start sensor.
E25: "Measure" sensor out of range. Check/clean this sensor !	The Measure sensor has reached a critical level. Continuing could result in wrong ESR results.	• Check and/or clean the Measure sensor.
E26: "Diluent Flow" sensor out of range. Check/clean this sensor !	The EDTA Flow sensor has reached a critical level. Continuing could result in	• Check and/or clean the EDTA Flow sensor.

	filling errors.	
E27: "Temperature" sensor out of range. Check Settings !	The measured room temperature has reached a critical level. Continuing could result in wrong ESR results.	• Check the temperature sensor setting. • Check and/or clean the Temperature sensor.
E29: Result path not found. Switched to default (D:\). Check "Result Path" setting.	Selected result path is not valid. Software is using the default setting	• Check result path setting • Check if network or USB devices are used.
E30: No ACK/NACK received from host after sending inquiry!	No response from Host within a certain time limit after sending an inquiry 3 times.	• Check communication cable between Host and StaRRsed Auto-Compact computer. • Check serial port settings (baud rate, etc...) • Check protocol settings. • Check Host computer.
E31: NACK received from host after sending inquiry!	Did not receive ACK from Host after sending inquiry 3 times.	See E30
E32: LIMS Connection timeout. Host not found!	The Compact could not establish a connection with the HOST (server) via TCP/IP.	• Check TCP/IP settings • Check network cable • Check HOST settings
		•
E34: No response from host after sending 'Sample data record'!	No response from Host within a certain time limit after 3 attempts.	See E30
E35: No response from host after sending 'Sample flag record'!	No response from Host within a certain time limit after 3 attempts.	See E30
E36: No ACK/NACK received after sending 'Sample result string'!	No response from Host within a certain time limit after 3 attempts.	See E30
E37: NACK received from host after sending 'Sample result string'!	Did not receive ACK from Host after sending 'Sample result string' 3 times.	See E30

E40: Position settings error. Settings loaded from Eeprom. Check settings before sampling!	Position settings in Eeprom do not match settings saved to file. Settings in Eeprom OK and loaded from Eeprom. Check positions and save settings.	• Configuration file maybe corrupted.
E41: Timeout settings error. Settings loaded from Eeprom. Check settings before sampling!	Timing settings in Eeprom does not match settings saved to file. Settings in Eeprom OK and loaded from Eeprom. Check timeouts and save settings.	• Configuration file maybe corrupted.
E42: Mixermotor current settings error. Settings loaded from Eeprom. Check settings before sampling!	Current settings in Eeprom do not match settings saved to file. Settings in Eeprom OK and loaded from Eeprom. Check current settings and save settings.	• Configuration file maybe corrupted.
E43: Motor settings error. Settings loaded from Eeprom. Check settings before sampling!	Motor settings in Eeprom do not match settings saved to file. Settings in Eeprom OK and loaded from Eeprom. Check motor settings and save settings.	• Configuration file maybe corrupted.
E44: Settings in Eeprom does not match with settings saved to file. Check settings before sampling!	Settings stored in Eeprom are OK and are loaded from Eeprom. Check Selected rack setting and save to file.	• Configuration file maybe corrupted.
E45: Settings in Eeprom not correct. Upload settings before sampling!	Checksum error on settings stored in Eeprom. Check Selected rack and save settings.	• Possible hardware failure in Eeprom.
E49:		
E50: Mixing error! Total amount of mixes not the same as setting. Check Mix-sensor or Rack timer setting T8 or T11.	Mixer could not do the correct number of mixes within a certain time limit. Timing settings T8 or T11 are too low or mixer (gripper) maybe blocked.	• Check rack timing settings T8 & T11. • Check mix sensor (+ distance). • Mixer is blocked. • Mixer motor is faulty. • Mixer motor driver on rack board is faulty.

E51: Mixer not back in its vertical position! Check if mixer is in the vertical position and clear error if OK!	Mixer could not come back in its vertical position after mixing.	• Mixer maybe hitting the bottom transport belts. • Mixer is blocked. • Mixer motor is faulty. • Mixer motor driver on rack board is faulty.
E54: Endpool full ! Remove all racks from endpool and then clear error!	This error will be cleared automatically after removing the racks from the end pool.	• End pool full. • Check Rack out sensor.
E55: Rack lost in endpool! Remove all racks from endpool and then clear error!	Rack is released from gripper but did not pass the End pool sensor.	• Rack maybe on its side. • Check End pool full sensor. • Check conveyer belt motor.
E56: Checksum error motor settings table!	Checksum error on motor settings stored in Eeprom. Settings are loaded from file. Check Motor settings and save settings.	Possible hardware failure in Eeprom.
E57: Checksum error current table!	Checksum error on current settings stored in Eeprom. Settings are loaded from file. Check Current settings and save settings.	Possible hardware failure in Eeprom.
E58: Checksum error time-table!	Checksum error on timing settings stored in Eeprom. Settings are loaded from file. Check Timeout settings and save settings.	Possible hardware failure in Eeprom.
E59: Checksum error position-table!	Checksum error on position settings stored in Eeprom. Settings are loaded from file. Check Position settings and save settings.	Possible hardware failure in Eeprom.
E60: Mixermotor error! (Hardware)	Could not home mixer motor.	• Check rack timing setting T1. • Mixer motor is faulty • Mixer motor is blocked. • Mixer motor driver on rack board is faulty. • Check mixer motor belt.

E61: Position motor error! Not on position! (OUT)	Gripper did not reach the OUT (release) position. Starting point: FILL position.	• Position (gripper) motor is faulty. • Position (gripper) motor is blocked. • Motor driver on rack board is faulty.
E62: Position motor error! Not on position! (MIX)	Gripper did not reach the MIX position. Starting point: OUT position.	See E61
E63: Position motor error! Home sensor!	Position motor did not reach the home position or could not detect home sensor.	• Check position (gripper) motor Home sensor. • Position (gripper) motor is faulty. • Position (gripper) motor is blocked. • Motor driver on rack board is faulty. • Check position motor belt.
E64: Position motor error! Not on position! (IN)	Gripper did not reach the IN (catch) position. Starting point: MIX position.	See E61
E65: Position motor error! Not on position! (MIX)	Gripper did not reach the MIX position. Starting point: FILL position.	See E61
E66: Gripper error! Rack not in gripper!	Follow the instructions on the screen.	• Check height of the tubes in the rack. • Check gripper sensor. • Check rack adapter.
E67: Position motor error! Not on position! (FILL)	Gripper did not reach the FILL position. Starting point: MIX or FILL position.	See E61
E68: Mixing motor current overshoot. Check if the mixer is blocked!	The mixer motor current exceeded the Maximum mixing current setting during mixing.	• Check mixer motor settings. • Mixer motor is blocked. • Mixer motor is faulty • Mixer motor driver on rack board is faulty. • Check mixer motor belt.
E69: Position motor error! Not on position! (MIX)	Gripper did not reach the MIX position. Starting point: IN position.	See E61

E70: Can't home mixer! Rack not on mix position!	Mixer motor send to home position, but position (gripper) motor is not on MIX position.	Check the position motor.
E71: Position motor error! Not on position! (MIX)	Gripper did not reach the MIX position. Starting point: HOME position.	See E61
E72: Not on position!	Gripper did not reach its given position by the user.	See E61
E73: Position motor error! Position motor is on IN position!	Could not send the racks on the In pool to the first stop position. Could not start the conveyer belt motor, because the position (gripper) is on the IN position.	Check the position motor.
E74: Position motor error! Not on position! (OUT)	Could not release the rack from the gripper, because the position (gripper) motor is not on the OUT position.	Check the position motor.
E75: Position motor error! Not on position! (IN)	Could not send (start the conveyer belt motor) the rack into the gripper, because the position (gripper) motor is not on the IN position.	Check the position motor.
E76: Can't start mixing (long)! Rack not on mix position!	Could not start the mixer motor, because the position (gripper) motor is not on the MIX position.	Check the position motor.
E77: Can't start mixing (short)! Rack not on mix position!	Could not start the mixer motor, because the position (gripper) motor is not on the MIX position.	Check the position motor.
E78: Mixer motor timeout! Mixer motor current level did not reach the stop level during homing action!	It is possible that the mixer did not came back to its home (vertical) position after mixing within a certain time limit.	• Check rack timing setting T1. • Mixer motor is faulty. • Mixer motor driver on rack board is faulty. • Check mixer motor belt.
E80:Position motor error! Not on position! (IN)	Gripper did not reach the IN (catch) position. Starting point: MIX position.	See E61
E81: Position motor error! Not on position! (MIX)	Gripper did not reach the MIX position. Starting point: IN	See E61

	position.	
E82: Position motor error! Not on position! (FILL)	Gripper did not reach the FILL position. Starting point: MIX position.	See E61
E83: Position motor error! Not on position! (MIX)	Gripper did not reach the MIX position. Starting point: FILL position.	See E61
E84: Position motor error! Not on position! (FILL)	Gripper did not reach the FILL position. Starting point: MIX position.	See E61
E85: Position motor error! Not on position! (FILL)	Gripper did not reach the FILL position. Starting point: last sampled tube.	See E61
E86: Position motor error! Not on position! (MIX)	Gripper did not reach the MIX position. Starting point: FILL position.	See E61
E87: Position motor error! Not on position! (OUT)	Gripper did not reach the OUT (release) position. Starting point: FILL position.	See E61
E88: Position motor error! Not on position! (MIX)	Gripper did not reach the MIX position. Starting point: OUT position.	See E61
E89: Position motor error! Can't initialize motor due to a possible hardware error! Please exit and then restart Auto-Compact. If this error occurs repeatedly, please note the error code before seeking assistance!	After an rack error the position motor tried to initialise its home position but could not succeed due to a possible fatal hardware error.	See E63
E90: Mixermotor error! Can't initialize motor due to a possible hardware error!	Could not home mixer motor within a certain time limit.	See E60
E91: Can not discharge rack! Endpool full, remove racks!	This error will be automatically cleared after removing the racks and the rack will be released.	• End pool full. • Check Rack out sensor.
E92: Position motor error! Not on position! (MIX)	Gripper did not reached the MIX position to start a short mix. Starting point: FILL position.	See E61

E93: Position motor error! Not on position! (MIX)	Gripper did not reached the MIX position. Starting point: FILL position.	See E61
E94: Position motor error! Not on position! (MIX)	Gripper did not reached the MIX position after reading the barcode. Starting point: FILL position.	See E61
E95: Position motor error! Not on position! (FILL)	Gripper did not reached the FILL position after mixing the rack. Starting point: MIX position.	See E61
E96: Position motor error! Not on position! (FILL)	Gripper did not reached the FILL position. Starting point: last sampled tube.	See E61
E97: Position motor error! Not on position! (IN)	Gripper did not reached the IN (catch) position. Starting point: MIX position.	See E61
E98: Position motor error! Not on position! (IN)	Gripper did not reached the IN (catch) position after gripper error. Starting point: MIX position.	See E61
E99: Position motor error! Not on position! (MIX)	Gripper did not reached the MIX position. Starting point: FILL position.	See E61
E100: Position motor error! Not on position! (MIX)	Gripper did not reached the MIX position. Starting point: IN position.	See E61
E101: Position motor error! Not on position! (FILL)	Gripper did not reached the FILL position. Starting point: last sampled tube.	See E61
E102: Position motor error! Not on position! (MIX)	Gripper did not reached the MIX position. Starting point: FILL position.	See E61

E104: Needle unit not in up position!	Could not start the position motor, because the outer needle or sample probe is not its home position (top).	• Check outer needle home sensor. • Check sample probe home sensor. • Faulty Outer needle motor. • Faulty Sample probe motor. • Check if needles are blocked. • Faulty motor drivers on the needle board.
E116-118	Quality Control Errors	See section ***Quality control trouble shooting*** (on page 85)

15. GLOSSARY OF TERMS

B

15.1.1.1.1. Bidirectional

Bidirectional communication means that there is two-way communication from the StaRRsed Auto-Compact to the HOST (sample requests and results) and from the HOST to the StaRRsed Auto-Compact (confirmation or denial of sample requests).

C

15.1.1.1.2. Citrate mode

Citrate mode is used for *pre-diluted samples* collected in tubes with *sodium citrate anticoagulant-diluent*. The samples are *not* diluted on the StaRRsed Auto-Compact during aspiration.
The concentration of sodium citrate within the diluent solution in the tube should be 3.2%. This is not to be confused with the required dilution rate of blood and diluent.
For example, in a citrate tube with a total draw volume of 1.6 ml (= 5 volumes), the amount of pre-filled diluent must be 0.32 ml (= 1 volume). If this information is not provided by the tube manufacturer, it should be checked by the customer.

E

15.1.1.1.3. EDTA mode

EDTA mode is used for *undiluted samples* collected in tubes with *EDTA anticoagulant*. The samples are automatically diluted on the StaRRsed Auto-Compact during aspiration. The usual amount of EDTA in sample tubes is 1.8 mg per 1 ml blood. 1 ml of blood weighs ca. 1060 mg and the concentration of EDTA is therefore 0.17% and well within the requirements for the EDTA mode on this instrument.

15.1.1.1.4. ESR

ESR is short for **Erythrocyte Sedimentation Rate.** It is the amount of sedimentation (setting) of erythrocytes (red blood cells) in a blood column during a specified time.

H

15.1.1.1.5. Hazy

A sedimentation is reported to be "**hazy**", when the boundary between blood plasma and erythrocytes can not be defined clearly.

15.1.1.1.6. Host

In this manual, the term **HOST** is used to indicate the computer system and associated software (LIMS) that provides the sample management for the laboratory.

I

15.1.1.1.7. IVD

IVD is short for **In Vitro Diagnostic.** This kind of diagnostic is performed on biological samples in a test tube, or more generally in a controlled environment outside a living organism. *In vitro* means *in glass* in Latin.

M

15.1.1.1.8. MRN

MRN is short for **Master Registration Number**. It is used as an identification number for any manual for Mechatronics products.

15.1.1.1.9. MSDS

MSDS is short for **Material Safety Data Sheet**. In this type of MSDS all kind of important data can be found on reagents.

T

15.1.1.1.10. Temperature correction

The sedimentation of blood cells is a temperature dependent process. To achieve comparable results, **temperature correction** should always be used. The ESR results are then corrected to the value they would have been at the *standard temperature of 18.3℃*.

U

15.1.1.1.11. Unidirectional

Unidirectional communication means that there is only one-way communication from the StaRRsed Auto-Compact to the HOST. Only sample results and result related messages are send.

W

15.1.1.1.12. WI

WI is short for **Work Instruction** and is used with an index number for a range of work instructions.

16. INDEX

V

W